UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

_____

| | |
|---|---|
| In Re: Bard IVC Filters Products Liability Litigation | MD-15-02641-PHX-DGC |
| | Phoenix, Arizona |
| | May 30, 2018 |
| | 12:57 p.m. |
| Doris Jones, an individual, Plaintiff, vs. C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants. | CV 16-00782-PHX-DGC |

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

(*Jury Trial - Day 10 - P.M. Session*)
(*Pages 2266 through 2381, inclusive.*)

Official Court Reporter:
Laurie A. Adams, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Suite 312
401 West Washington Street, Spc 43
Phoenix, Arizona 85003-2151
(602) 322-7256

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

APPEARANCES:

For the Plaintiff:

GALLAGHER & KENNEDY PA
By: Mark S. O'Connor, Esq.
By: Paul L. Stoller, Esq.
By: Shannon L. Clark, Esq.
By: C. Lincoln Combs, Esq.
2575 East Camelback Road, Suite 1100
Phoenix, Arizona 85016

LOPEZ MCHUGH LLP
BY: Ramon Rossi Lopez, Esq.
By: Joshua Mankoff, Esq.
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

HEAVISIDE REED ZAIC
By: Julia Reed-Zaic, Esq.
By: Laura Elizabeth Smith, Esq.
312 Broadway, Suite 203
Laguna Beach, California 92651

For the Defendants:

NELSON MULLINS RILEY & SCARBOROUGH LLP
By: Richard B. North, Jr., Esq.
By: Elizabeth C. Helm, Esq.
By: James F. Rogers, Esq.
201 17th Street NW, Suite 1700
Atlanta, Georgia 30363

I N D E X



INDEX OF EXHIBITS

P R O C E E D I N G S

THE COURT: All right, counsel. I have thought about the request from plaintiff on more time. I could not agree -- I could not disagree more with the suggestion you made, Mr. O'Connor, that you should get time back because you have been forced to expend it at sidebars or due to evidentiary rulings. The longest sidebar we had was maybe five minutes. Most have been two or three. They have all been on evidentiary issues in the case. The longest discussions we have had have all been off the clock when the jury is out of the courtroom. And I'm not aware of any evidentiary ruling that has required you to put in more evidence. So I absolutely disagree with that suggestion. 12:57PM 12:57PM

I have been watching closely the plaintiff's case. I believe plaintiff's attorneys have done a much better job in this case than Booker of using their time wisely. There's been little repetition. There was a lot of repetition in Booker. There have been several witnesses I noted that I thought could have been done more quickly, but that's a strategic call. 12:57PM

So I don't believe plaintiffs have wasted time. I said in my order I wouldn't bail them out if they did. I don't believe they have. I believe they have been efficient so I am going to grant one additional hour of time to plaintiff for purposes of completing the case. 12:58PM

MR. O'CONNOR: Thank you. 12:58PM

THE COURT: And we'll bring in the jury.

(Jury in at 1:00 p.m.)

THE COURT: We will continue, Ladies and Gentlemen, with the video that was being played before the noon hour.

(Video testimony of William Little resumed.) 01:04PM

MS. HELM: Your Honor, at this time the defendants call Dr. Scott Trerotola by video. There are no exhibits with this deposition.

Dr. Trerotola is a board certified radiologist with a specialty in interventional radiology. He maintains a clinical 01:09PM practice in interventional radiology at the Hospital of University of Pennsylvania where he has been chief of the Radiology Department since 2001.

He graduated from the University of Pennsylvania Medical School in 1986 and has been implanting IVC filters 01:09PM since the 1990s. And he has been retrieving optional filters since they first came on the market in the early 2000s.

MR. CLARK: I'm sorry, Your Honor. That did not include a sentence that we also added on there.

The proposed sentence was to the effect that he has 01:10PM also served as a paid consultant for Bard over the years.

THE COURT: Okay. Thank you.

(Video testimony of Scott Trerotola, M.D. played in open court.)

MR. NORTH: Your Honor, at this time Bard would call 01:14PM

its final witness, Mr. Chad Modra to the stand.

THE COURT: If you want to stand up, Ladies and Gentlemen, while he's coming in, feel free.

Mr. Modra, you are still under oath for purposes of the trial, so you can come directly back to the witness stand. 01:22PM

THE WITNESS: Thank you.

CHAD MODRA,

called as a witness herein, having been previously sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. NORTH:

Q. Good afternoon, Mr. Modra.

A. Good afternoon.

Q. Could you tell the members of the jury how long you have worked with Bard? 01:22PM

A. 17 and-a-half years.

Q. And what is your current title at Bard?

A. Continuous Improvement Leader.

Q. And what do you generally do in the position as Continuous Improvement Leader? 01:22PM

A. Well, because of my knowledge of Bard and the processes that we have, I have a task to find ways to improve either the processes, the systems, the efficiencies, the way we do things.

Q. At one point were you working specifically with the division Bard Peripheral Vascular? 01:23PM

A. I was.
Q. And were you the Vice President of Quality at that division?
A. I was.
Q. And while you were at Bard Peripheral Vascular, what products did you work on? 01:23PM
A. Filters, of course; stents; grafts; PTA balloons; dialysis catheters; ports; biopsy needles.
Q. Please describe for the jury your role and your responsibilities as the Vice President of Quality. 01:23PM
A. Well, as the Vice President of Quality, all of the quality department reports to me. So the Quality Department is sort of a check and balance and a participant in all the things that go on at the facility, both from a manufacturing design and systems standpoint. We're typically in charge of 01:23PM investigations. We also handled post-market surveillance, which is complaint handling, event handling, experience from the customers' experience from clinicians and processing of those and making sure that we maintain compliance with the regulations. 01:24PM
Q. So as a part of your role as the Vice President of Quality did you generally oversee the investigation of complication reports?
A. I did.
Q. Did you also review trending and tracking of those 01:24PM

complications?
A. I did.
Q. And did that job extend to the IVC filters?
A. It did, amongst all the other problems we had.
Q. Where did you grow up, Mr. Modra? 01:24PM
A. In the midwest.
Q. Where do you live now?
A. In Phoenix.
Q. How long have you lived in Arizona?
A. Seven years next week. 01:24PM
Q. Can you describe for the members of the jury your educational background?
A. I have a Bachelor of Science in Mechanical Engineering from Purdue University.
Q. And you have worked in the medical device industry since 1994? 01:25PM
A. That's correct.
Q. When did you first join any part of Bard?
A. I joined Bard first in August of 2000.
Q. And tell us who you worked for before August of 2000. 01:25PM
A. For Abbott Laboratories. They were a company in the midwest.
Q. What did you do for Abbott Laboratories?
A. I was on a development program where I went to different sites for a period of time and learned their processes. I 01:25PM

worked on baby formula. I worked on pharmaceuticals and also mechanical or medical devices.

Q. And when you first joined Bard in 2000, tell us where you worked within the Bard family.

A. In the Bard Access Systems, which is just another location in Salt Lake City of Bard. They make different kinds of products. 01:25PM

Q. What kind of products did you work with at Bard Access Systems?

A. At the time, peripherally inserted catheters, so catheters they put in your lower arm or upper arm. We had originally developed the dialysis catheters there, the cancer ports there as well, feeding catheters. 01:26PM

Q. At Bard Access, did you work in the Quality Department?

A. I did. 01:26PM

Q. And what sort of positions did you hold within the Quality Department add Bard Access?

A. I went there originally as a senior quality engineer working in the new product development area, so developing new products. And I held positions of manager, senior manager, director of quality engineering. 01:26PM

Q. And what was your highest position before you left Bard Access?

A. Director of Quality Engineering.

Q. And did you go from Bard Access here to Tempe for Bard 01:26PM

Peripheral Vascular?
A. I did.
Q. And when did you make that move?
A. In -- I joined in March of 2011. My family joined me shortly thereafter. 01:27PM
Q. And you stayed at Bard Peripheral Vascular for how long until you took this broader role?
A. Until December 2015. I was asked to take a more broad role.
Q. Mr. Modra, why have you decided to devote your career to medical devices? 01:27PM
A. I thought about that a lot, and there's a lot of things you can do. I feel like you can make a lot of things. You can design a lot of things, which is already exciting. But I feel like if you can design something that's helping people. A lot of times these devices are used on friends, family, so that's a big responsibility. So that's the great thing about it. You feel like a proud parent when your device is used on them. 01:27PM
MR. O'CONNOR: Objection, Your Honor. I move to strike that response for reasons that were raised in the motion. 01:27PM
THE COURT: Let's talk at sidebar for a minute, counsel.
If you want to stand up, Ladies and Gentlemen, feel free. 01:28PM

(Discussion was had at sidebar out of the hearing of the jury:)

THE COURT: My memory, Mr. North, is I specifically ruled on use of devices in friends and family.

MR. NORTH: He went much further than I had any anticipation he was going to. 01:28PM

THE COURT: I think I should instruct the jury to disregard his last answer.

MR. NORTH: That's absolutely fine. I apologize.

(In open court.) 01:28PM

THE COURT: Thank you, Ladies and Gentlemen. Please have a seat.

I'm going to instruct you to disregard the witness's last answer.

Go ahead, Mr. North. 01:28PM

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q. Mr. Modra, was your first experience with IVC filters when you came to Bard Peripheral Vascular in 2011?

A. It was. 01:28PM

Q. How soon after you started at Bard Peripheral did you have exposure or begin working on projects involving filters?

A. During my transition time my predecessor and I had discussions on all sorts of products, including IVC filters. So it was in the springtime of 2011. 01:29PM

Q. And as you became familiar with IVC filters, did you also become familiar with the fact that there were some reports of complications with the device?
A. Yeah. That was part of the, I guess, transition is understanding a little bit of the history but also the benefits and risks involved in them. 01:29PM
Q. During the 20-plus years you have been involved with the medical device industry, have you ever worked on any devices that did not carry at least some risk of complications?
A. No. 01:29PM
Q. As a part of your role as the Vice President of Quality at Bard Peripheral Vascular, what were your responsibilities regarding the development of policies and procedures for the department?
A. Ultimately, I'm responsible for ensuring that those are written in a manner that can be followed, are followed, and are compliant to regulations and laws. 01:30PM
Q. And did you have responsibility to be familiar with past practices and policies for the Quality Department?
A. I did. 01:30PM
Q. Does Bard have policies and procedures that govern how complaints or complication reports are handled?
A. Yes. Quite a few.
Q. In your business and work within the Quality Department, did you generally use the term "complaint" to describe a report 01:30PM

you might receive of a complication with a device?
A. Generally complaint, complaint event.
Q. If we could bring up Exhibit 7961, please.
Do you recognize this document?
A. I do. 01:31PM
Q. What is this document?
A. It's the standard for how to handle product complaints that's used by BPV, or Bard Peripheral Vascular.
MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 7961. 01:31PM
MR. O'CONNOR: No objection.
THE COURT: Admitted.
BY MR. NORTH:
Q. Mr. Modra, what is Bard's overarching or ultimate goal for processing incoming complaints? 01:31PM
A. We want to make sure that, one, we're compliant to all regulation. But the end goal of it is really to understand customer experience, the patient experience, and the clinician experience and understand if there is any safety signals, failure modes that are happening with those and the ability to 01:31PM track and trend those.
Q. Does this policy for complaint handling that Bard has in place, would that also extend to complication reports regarding IVC filters?
A. It would. It would be for all products. 01:31PM

Q. What departments at Bard are responsible for receiving complaints?
A. Well, really, all departments are responsible for receiving them, meaning if they hear of any incident, even casually in literature, they are responsible for reporting that to what we call the Field Assurance Department. So they will take that information from whoever gives it to them and write the report and begin the investigation of that event. 01:32PM
Q. Does the Field Assurance Department, is that part of the quality group that you headed up? 01:32PM
A. It is.
Q. And did the Field Assurance Group report to you?
A. They did.
MR. NORTH: Your Honor, could we publish Exhibit 7961?
THE COURT: Yes. 01:32PM
BY MR. NORTH:
Q. What are the various sources of complaints or complication reports that the Field Assurance Department might receive?
A. It could be from anywhere, but primarily it's literature. It's sales reps. Its doctors directly. It's FDA. It's patients, they call them in. So any of those. 01:33PM
Q. Do doctors sometimes report complications directly to Bard?
A. Rarely, but on a few occasions I know they do.
Q. Do sometimes patients report complications?
A. Not typically. Not directly. Usually it's the hospital. 01:33PM

Even the risk manager in the hospital will send it either to us directly or our sales rep based on information they received from a doctor.

Q. If a sales rep calls upon a doctor to discuss Bard's products and the doctor mentions some adverse event that occurred in his or her practice recently, would that be reported? 01:33PM

A. Yes.

Q. And what sort of training do you give the sales representatives to report anything they hear concerning an adverse event? 01:33PM

A. They go through procedural training as well as a slide presentation that I used to give at their conference events to make sure that they are aware of their responsibility for once they hear about any sort of complaint, any sort of alleged issue that they immediately send it to the field assurance area. 01:34PM

Q. You mentioned the literature. Does Bard generally keep an eye on medical journals in the fields where it makes products to service or to assist those doctors? 01:34PM

A. We do. We do. We review them periodically to look for these sorts of events.

Q. If your department were to learn of an article, let's say, in the SIR's publication regarding complication incidents with Bard filters, would those be investigated by your team? 01:34PM

A. They would. And we would look to see if they had already crossmatched it to an event that may have already been reported.
Q. Now, does Bard also have a service called MS&S?
A. They do. 01:35PM
Q. Tell us what MS&S stands for.
A. I believe it's a Medical Service and Support. And really they are on the other end of an 800 line, 1-800 line where anyone can call in and if they have any sorts of questions regarding the products or if they want to report a complaint 01:35PM
event, they call that number and then it's triaged by asking a few simple questions, whether it's just a comment that they receive or whether it's -- could be related to a complaint. If it's related to a complaint then MS&S transfers it to the field assurance area. 01:35PM
Q. Is MS&S physically located in Covington, Georgia, outside of Atlanta?
A. Yes.
Q. If a call were to come in to 1-800 number and it's picked up by somebody at MS&S, and let's say it's a doctor on the 01:35PM
other side or a patient reporting some complication with a Bard device, would that word of that call then make it to your department?
A. Yes.
Q. And would your department then investigate that call? 01:36PM

A. Yeah. They take it from there. They get all the contact information from the person that called in regardless of who it is. And then the Field Assurance Group has procedures where they will go back and follow up and get additional information as much as they can from every event. 01:36PM

Q. With regard to IVC filters, was there any pattern or trend you saw over the years as to when complications might be first perceived?

A. Typically they are at retrieval. That's where I have seen them most reported. 01:36PM

Q. In your experience over the years, were most of the complaint or complication reports received by the company regarding IVC filters, were most of those asymptomatic or symptomatic?

A. Asymptomatic. 01:37PM

Q. Over the years, did Bard sometimes compare its internal complication reported rates among various filters?

A. We have from time to time, yes.

Q. And did that sometimes include comparing the complication reports you had received regarding the Simon Nitinol Filter 01:37PM with the reports you had received regarding the, let's say, Eclipse Filter?

A. Yes.

Q. And do you think that was always a fair comparison?

A. It's not really the same thing. They have different 01:37PM

indications. So they are both filters, but you just -- yeah. It's not really all that close.

Q. In your experience were Simon Nitinol Filters that had been implanted monitored as closely as retrievable filters?

MR. O'CONNOR: Objection. Lack of foundation. 01:38PM

THE COURT: Overruled.

THE WITNESS: Not typically.

BY MR. NORTH:

Q. Once field assurance receives a report of a complication, are there circumstances where other departments in Bard become 01:38PM involved in analyzing or investigating the incident?

A. Yeah. Field assurance is really the point people that take the narrative of the event. They ask -- they are trained to ask those questions specifically to get as much detail. But based on the narrative we get quality engineering involved, we 01:38PM get research and development engineers involved, we get some of the other product designers and experts involved and try and determine what might be the cause of the situation. So it's any number of folks across the organization would be involved in that. 01:38PM

Q. In what ways does the Field Assurance Department work with research and development, for example, in assessing and learning from complication reports?

A. Well, by analyzing across all of the reports that we get, you can really understand maybe the way the devices are being 01:39PM

used, maybe the way they are not being used, what kinds of complications you might have. And that's great information to give back to the research and development because when you have a continuum of product improvements, you have great new ideas and you get a lot of those just from the experiences you hear in post-market surveillance. 01:39PM

So they have a pretty good and a routine discussion period like every two weeks where they have time set aside to kind of share that information back and forth.

MR. NORTH: Your Honor, could we display again 7961? 01:39PM

THE COURT: Yes.

MR. NORTH: Could we turn to Page 5, please.

BY MR. NORTH:

Q. Does this standard that Bard has outline a procedure for the investigation of the complaints? 01:40PM

A. It does.

Q. And when a complaint is received, what steps does field assurance take to investigate it?

A. Well, first, they take that information that they have to start with. They have to make a decision whether it really is 01:40PM a complaint and then also whether it's reportable to FDA. And there's a certain percentage of those that are reportable that are covered under another standard. But they walk through just basic questions: Is there an alleged deficiency, as it says here; what was the situation that was happening at the time of 01:40PM

the event; is it a product suggestion, you know. We take those as well, but that wouldn't necessarily be a complaint. And so they work through these series of questions, take down the narrative, and then begin to try and get all that information, the patient information, the doctor information, what they were seeing, what they were observing at the time, and then they try to get the device back if it's possible. Because we have a lab we can do some testing on it, measurements and things to see if it's remained within specification. 01:40PM

MR. NORTH: If we can go to Page 6, please. 01:41PM

BY MR. NORTH:

Q. Does this particular standard that's contained in Exhibit 7961 set forth in great sort of step-by-step detail the method utilized to investigate complication reports?

A. It includes the details of all the things we need to include in a complaint investigation and those are used in complication reports, so yes. 01:41PM

Q. Now, does Bard make an attempt if it's a device that has failed in some way, make an attempt to get the actual device back from the physician or from the hospital? 01:41PM

A. We do. The typical target is always three attempts to get information and the device back. And so you would maybe call, leave a message, or you would try to get that device back from the person, from the risk manager, from the hospital, whoever may have it. So it's a little bit of tracking people down, but 01:42PM

they are pretty persistent. So we try to get as many back as we can because then you can do more analysis on it.
Q. Well, if you do succeed in getting the device back at Bard, what do you do with it?
A. We have an analysis lab, and we have high precision equipment to measure it, to observe it, take pictures. We can do some minor testing on it. Unfortunately, after a device has been used, typically, if it's failed it's been compromised or it's been -- we don't know exactly how it's been handled but we do have a pretty comprehensive lab to be able to do testing on it. 01:42PM 01:42PM
Q. Now, does the FDA have a set of codes that you are supposed to utilize in classifying complication reports?
A. Yes, they do.
Q. And are those by failure mode? 01:43PM
A. They are. Some are more general than others, but they are descriptive enough to use consistently in products.
Q. And do you use those FDA codes for internal trending and tracking of adverse complications?
A. We do. Regardless of the severity of the complication, the good thing about the codes is you can put multiple codes in a single event. So instead of reading through every complaint that you get and you look at a narrative you can kind of boil it down to the codes that are used. And that way you can track and trend those across all the multiple events. 01:43PM 01:43PM

Q. Is there a particular code FDA has used to govern a report of a fracture with a device such as an IVC filter?
A. They have.
Q. And what is that particular code called?
A. I think it's detachment. I think that's the term, detachment. 01:44PM
Q. Now, once the Field Assurance Department has collected all the information they can and analyzed that information in conjunction with engineers and research and development personnel, does the company have to make a decision as to whether to report that event to the FDA? 01:44PM
A. We do.
Q. And does the FDA have certain regulations that govern when you have to report adverse events to the agency?
A. Yeah. There's criteria called MDR, Medical Device Reporting requirements. 01:44PM
Q. How do you go about doing that? Do you call the FDA up on the telephone? Submit something electronically? File a written report? How does that work?
A. In the last couple years they have gone to E-MDR so they are all submitted electronically. In the past, they were submitted via a certain form that they have, 3500A form. But it has certain fields that you fill out, and once you have determined it to be a reportable based on a series of questions, I think there's maybe 11 or 12 questions that we 01:44PM 01:45PM

have based on the regulation, then you have to report it. So if you report it now then it is electronically reported.

MR. NORTH: Could we bring up Exhibit 7962, please.

BY MR. NORTH:

Q. Can you tell us what 7962 is, Mr. Modra? 01:45PM

A. It's similar to the other standard but it's the standard that includes instructions for when to and how to report the MDR record to FDA.

Q. And is that the standard that your department followed in making determinations as to whether to report adverse events to 01:45PM the FDA?

A. Yes.

Q. And was this standard created to comply with the FDA's regulations?

A. Yes. 01:46PM

MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 7962.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

MR. NORTH: Could we display, Your Honor? 01:46PM

THE COURT: Yes.

BY MR. NORTH:

Q. Mr. Modra, does Bard report to the FDA only those complaints that occur in the United States or also those that occur outside of this country? 01:46PM

A. We actually report those that are on similar devices outside the country. So even though the situation didn't occur within the United States, they have the requirement that if you have a similar device sold here, even though the event happened somewhere else, you have to report an MDR as well. 01:46PM

Q. Let's look at Page 2, a series of definitions in the corporate -- or the Bard standard. At the bottom of the page there is a definition for malfunction. Tell us why that's important.

A. When you are reporting an MDR, you have to report it as either a malfunction or a serious injury. And the definition is important because that's the definition with which FDA uses to determine reportability, they say if it meets this definition you have to report it. 01:47PM

Q. So even if you decide that the event should be characterized as a malfunction and not as a serious injury, is it still reported to the FDA? 01:47PM

A. Yes.

Q. Okay. If we could turn to Page 4, please.

Is there also at 4.20 a definition for serious injury? 01:47PM

A. There is.

Q. Now, did Bard come up with these definitions for malfunction and serious injury itself, or what were you counselled by in coming up with these definitions?

A. These are from the FDA themselves, so they publish both the 01:48PM

regulation but then also subsequent guidelines that they send out that helps manufacturers guide them on the interpretation of what the regulation is. So it's from that.
Q. What sort of events are not reported to the FDA at all?
A. Non-malfunction, non-serious injury, more minor severity events. Maybe if someone doesn't like the color of a device, we still -- we don't report it unless it's related to some impact to the patient. But we still keep it tracked as a complaint, because that's information that either the clinician or the patient have provided to us. 01:48PM
Q. Devices such as IVC filters are sterilized before they are packaged, aren't they?
A. Yes.
Q. If a device, let's say an IVC filter, was opened by the doctor and the packaging had been ripped somehow, perhaps in shipment, and they reported that, would that be reported to the FDA? 01:49PM
A. Yeah. It's a sterile breach of barrier.
Q. So even if there's no impact on the patient, that sort of event would be reported? 01:49PM
A. Yeah. Yeah.
Q. And did -- well, regardless of whether you characterize under this standard an event as a malfunction or as a serious injury, is it nevertheless reported to the FDA?
A. Yeah, both of those. Anything in those two areas are 01:49PM

definitely reported.
Q. Now, on those very minor reports such as somebody complaining about the color of a device like you mentioned, and you are having to make the decision whether to report the complaint to the FDA, how many Bard employees are involved in making that determination? 01:49PM
A. Typically at least three: One, the person that has taken down the narrative; then there's a field assurance check, so that person will check to make sure that the record is completed correctly, that all the narrative is appropriately filled out; and then there's a third person that is a quality check that, again, takes a look at that and then looks at the decision making as well. 01:50PM
Q. If Bard cannot determine whether the information provided rises to the level of the FDA's requirement to file a medical device report, or MDR, what does Bard's policy require in terms of whether to report? 01:50PM
A. If there's any question about it you need to report it, if you can't rule it out. Like in the example of a color, if even someone may not like the color, but if the narrative includes the fact that they didn't like the color and it caused them to choose something incorrectly, that could be a reportable incident. So you would have to report that. 01:50PM
Q. After making -- how quickly does Bard report a -- report to the FDA information regarding, let's say, a serious injury or 01:51PM

malfunction that the company has learned about?
A. You have got 30 days. There's a 30-day time requirement that you have got to report it. So you have got to try and get that information pretty quickly, you know, the three attempts to get it back and determine what really has happened in the event and then put together whatever information you can to make that decision within the first 30 days. 01:51PM
Q. If after that 30-day period Bard were to receive additional information regarding an adverse event, what do you do with that new information? 01:51PM
A. You document it. There's a process where we go through the record and then let's say you get more medical records, you get additional information from the hospital, you have to include that back in the record. So you open it back up, and then again, you go through the same process. Is it reportable? If it's reportable then you have got to file it. 01:52PM
Q. Now, we were talking earlier about sources of information, or where sources of information regarding adverse events might come that would initiate an investigation. Let's say a lawsuit was filed like Ms. Jones filed the lawsuit here. When you received, your company, that lawsuit, would you also initiate an investigation regarding that claim? 01:52PM
A. We would.
Q. Mr. Modra, we have been talking about complications and the policy we were looking at a few moments ago about when to 01:53PM

report those to the FDA and when not to. With regard to IVC filters, did Bard report each and every report of a fracture it received?

A. To my knowledge, yes.

Q. What about with regard to each and every report of migrations of a filter? 01:53PM

A. Yes.

Q. And what about a perforation?

A. Yes.

Q. And what about a tilt with regard to a filter? 01:53PM

A. Yes.

Q. Now, does Bard periodically compute or trend and track the adverse events that you have become aware of?

A. Yes.

Q. And do you try to determine what the rates of complication reports are that you have received as compared to the sales of particular products? 01:53PM

A. We do.

Q. What's your purpose in doing that trending and tracking internally? 01:54PM

A. Well, one, it's the best way to understand if the product is performing as you would expect compared to previous estimates and to see if there's anything out of the ordinary that has occurred.

Q. Now, do you sometimes review the -- well, tell us what the 01:54PM

MAUDE database is.
A. It's an acronym, I believe, on the FDA website. And it's when we report these MDRs they go to FDA and they are placed in the MAUDE database. So it's a public record. You can search it for any type of device or time period or manufacturer. 01:54PM
Q. On occasion, has Bard reviewed data from the MAUDE database?
A. We do.
Q. Do you review the information in the MAUDE database regarding competitive products? 01:55PM
A. You do.
Q. And have you, on occasion, looked to see what you can find in the MAUDE database with regard to other filters manufactured by other companies?
A. Yes. 01:55PM
Q. Now, when you analyze that sort of data, do you share those rate calculations either internally as to Bard's products or any attempt to compare what you see on the MAUDE database with other products? Do you provide that information to physicians?
A. No. 01:55PM
Q. And why is that?
A. Well, one, we can't because anything you share with a clinician, it's just like the advertising requirements. It's got to be fair, balanced, and clinically relevant or clinically based. So even with the MAUDE database there's a disclaimer 01:55PM

right on the FDA website that says don't do that, don't share it, or don't make comparisons strictly on this data alone. And also, the estimates of the sales or the denominator for that rate isn't included in the MAUDE database. So those are estimates that we would have to get from somewhere else. 01:56PM

MR. NORTH: Could we bring up Exhibit 7795, please. I believe this has already been admitted.

THE COURT: Yes.

MR. NORTH: Could we display to the jury, please?

THE COURT: Yes. 01:56PM

BY MR. NORTH:

Q. Mr. Modra, is this the part of the FDA website or from the MAUDE database that you were discussing?

A. It looks like it is, yes.

Q. If we could highlight the second bullet point here. Is this what you were referencing earlier as to how MDR data or the FDA says MDR data alone cannot be used to establish rates of events? 01:56PM

A. It was.

Q. Well, let's say even if you looked at the MAUDE database and you learned that there had been 10,000 complaints with a Cook inferior vena cava filter, you wouldn't be able to determine what their complication rate is unless you also knew the number of filters that Cook had sold, correct? 01:57PM

A. Correct. I mean that -- an absolute number as just 01:57PM

reported on here, we don't know necessarily the denominator.
Q. You mentioned the IMS data. What is that?
A. IMS, I forget the acronym, what that stands for, but it's a service where you can get competitive data, sales data. So you could make some estimates based on that, but there's still, as I understand it, a quarter lag, meaning a three-month lag in those estimates plus you don't know how accurate they are. So there's always some variability in those. 01:57PM
Q. So would you consider any complication rate of a competitive filter derived from looking at the MAUDE database for the number of events and the IMS data for a projection of sales to be a reliable rate? 01:58PM
A. It might be interesting, but it's not to a suitable scientific level where you could publish that sort of thing or share that anywhere. 01:58PM
Q. Now, would you, as a quality assurance professional in the medical device industry, feel comfortable in putting competitive rate data based on the MAUDE database and IMS sales projections into an IFU?
A. No. Not at all. 01:58PM
Q. Do you believe that it would be appropriate to do so in accordance with your understanding of what the FDA requires for medical device companies?
A. No. I don't think that would be allowed at all.
Q. Do you think it would be appropriate for Bard to share rate 01:59PM

projections or calculations based on MAUDE data of other manufacturers' devices and IMS projections in handouts to physicians and hospitals?
A. No.
Q. Over the 20-plus years you have worked in the medical device industry, are you aware of any device manufacturer that that has included its internal complication rates within its Instructions For Use? 01:59PM
A. No.
Q. What is a DFMEA? 01:59PM
A. Design Failure Modes Effects Analysis tool.
Q. Is that a quality assurance analysis tool that you used at Bard to assess risks associated with various products?
A. I would even make it more broad than that. Not just quality assurance but it's a tool that's used to assess potential risks and occurrence rates for those failure modes related to those risks. 02:00PM
Q. Over the 20-plus years you have worked in the medical device industry, are you aware of any device manufacturer that has included its DFMEA calculations within its Instructions For Use? 02:00PM
A. No.
MR. O'CONNOR: Objection. Lack of foundation.
THE COURT: I couldn't hear what you said, Mr. O'Connor. 02:00PM

MR. O'CONNOR: I'm sorry, Your Honor. Lack of foundation.

THE COURT: Hold on just a minute.

Overruled.

THE WITNESS: No. I'm not aware of any. 02:00PM

BY MR. NORTH:

Q. During your 20-plus years in the medical device industry, have you ever seen an instance where any medical device manufacturer disclosed its internal calculations of complication rates in an IFU? 02:00PM

A. No. Not that I'm aware of.

Q. Mr. Modra, periodically, does Bard conduct internal audits of its own complaint handling systems?

A. We do. We conduct internal audits as well as a lot of other audits. We're subjected to a lot of other audits, 02:01PM external audits as well.

Q. How often does Bard conduct internal audits?

A. Of just that area or all the areas every year?

Q. Of all the areas?

A. We have in our practices where we conduct audits of all the 02:01PM different areas in the business in a calendar year.

Q. Does Bard sometimes retain third parties, outside private consultants, to come in and audit your various processes?

A. Yes.

Q. Have you done that periodically over the years with your 02:01PM

complaint handling process?
A. Yes.
Q. How rigorous are these audits that are internally conducted or conducted by consulting firms hired by Bard?
A. Pretty thorough, because they will pull a pretty deep sample of records. They will go through each record. They sit down and not just look at are people following the procedure but is the procedure correct. So in my experience they are not afraid of running up observations. 02:02PM
Q. Now, after the FDA clears a device that comes to market through a 510(k), does the FDA, is it finished with the device or does it continue to be involved with the device in the company? 02:02PM
A. They are always involved in the company.
Q. Does the FDA itself conduct audits of medical device companies? 02:02PM
A. They do.
Q. What sorts of audits does the FDA perform?
A. Typically they will be -- I don't know if the right term is periodic, but the schedule is usually about every two years, two, maybe three at the most, and they are usually unannounced audits. So, I mean, you are ready at any time. FDA can show up at your door at 9 a.m. and you just escort them right to a conference room, and it's all hands on deck. So whatever they want, everyone knows that that's -- they get what they want. 02:02PM 02:03PM

Q. As the Vice President of Quality Assurance, how does it feel to sit at your disk at 9 a.m. having a cup of coffee and have the receptionist tell you the FDA is in the lobby of the building?
A. My coffee usually gets cold after that. 02:03PM
Q. Are these audits by the FDA routine?
A. Yeah. Like I said, typically every two years. They can schedule them at any time, though, for Bard Peripheral Vascular because we had device submissions. They would come even more frequently than that. 02:03PM
Q. Are all -- does the FDA conduct these sorts of audits of all medical device companies?
A. Yes.
Q. Does the inspection process sometimes result in an FDA finding of deficiencies in your various quality systems? 02:04PM
A. It does.
Q. During your time at Bard Peripheral Vascular, was the company subject to some of these periodic routine FDA audits?
A. Yes.
Q. And did the FDA, as a result of some of those audits, issue 02:04PM a warning letter to Bard Peripheral Vascular while you were employed with the company?
A. They did.
Q. And when was that?
A. July 13th, 2015. 02:04PM

Q. You seem to remember that date well.
A. I do.
Q. In your experience, are FDA warning letters rare?
A. Maybe in the past, but not so much anymore.
Q. Is that something that's only happened to Bard or has it happened to some of your competitors in other major medical device companies in the industry? 02:04PM
A. It happens to most all the ones I'm aware of.
Q. Now, was the warning letter issued in July of 2015, was that related to the complaint processing systems, at least in part? 02:05PM
A. In part, yes.
Q. Now, prior to the inspection in the 2015 time frame, the audit, had BPV or Bard Peripheral, ever been audited by the FDA before? 02:05PM
A. Yeah. Twice since I had been there, so twice since March 2011.
Q. And had you personally met with FDA auditors in the past while working at Bard Peripheral Vascular?
A. I did. 02:05PM
Q. And on those two occasions when the company was audited prior to 2015, what were the results of those audits of the company?
A. No observations.
Q. Had the policies or procedures or ways you did your 02:06PM

business changed since those two audits where there were no observations until 2015?
A. Not substantially.
Q. Prior to 2015, to your knowledge had Bard Peripheral ever received an FDA warning letter? 02:06PM
A. Not that I'm aware of, no.
Q. Were you surprised when the company received that warning letter?
A. I was, given I was involved in the thoroughness at which we had answered previous observations. We had covered not just 02:06PM what they had -- we believed they had an issue with but also looked around and made other system-wide significant changes. So I really thought that, you know, it had been an extended time period between when we received the observations and the warning letter. So I felt like maybe we had addressed the 02:07PM their concerns adequately. And we hadn't heard anything back from them during the entire time period.
Q. If we could bring up Exhibit 1680, please.
MR. NORTH: I'm sorry. Bring that up. Let me see the second page, if you could. 02:07PM
Okay. Go back to the first page.
BY MR. NORTH:
Q. Do you recognize Exhibit 1680?
A. I do.
Q. And is this the warning letter from the FDA that we talked 02:07PM

about?
A. It is.
Q. And who is it addressed to?
A. Timothy M. Ring.
Q. And he was the Chief Executive Officer of Bard at the time? 02:07PM
A. He was.
MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 1680 as redacted.
MR. O'CONNOR: No objection.
THE COURT: Admitted. 02:07PM
BY MR. NORTH:
Q. Let me ask you some questions about this warning letter, Mr. Modra. Did this warning letter in any way address whether there was any defect in the design of Bard's Recovery Filter?
A. No. 02:08PM
Q. Did it in any way address whether there was any defect in the design of Bard's G2 Filters?
A. No.
Q. And did it in any way address whether there was any design defect in the Eclipse Filter? 02:08PM
A. No.
Q. Did it in any way address whether there was a defect of any sort in the warnings provided by Bard with regard to the Recovery Filter, the G2 Filters, or the Eclipse Filter?
A. No. 02:08PM

Q. Did it in any way suggest that Bard's Recovery Filter, G2 Filter, or -- G2 filters or Eclipse Filter were unsafe?
A. No.
MR. O'CONNOR: Objection. Irrelevant, Your Honor.
THE COURT: Overruled. 02:08PM
BY MR. NORTH:
Q. Mr. Modra, there was some discussion in the warning letter regarding an issue with misreporting of an event associated with a patient death. Do you know what happened regarding that? 02:09PM
A. Yes.
Q. Tell us what happened there.
A. We had received the initial complaint and filed it as a reportable event, but at some point in time later we had received additional information that said that the patient had 02:09PM died. And between the files that we had in house and the way we reported it on the MDR form, it was a paper form at the time, the box that said patient had died was not checked. So there was inconsistency between what was reported and our internal paperwork. 02:09PM
Q. Over the years, has the FDA clarified its position on what events should be filed with the FDA?
A. It has.
Q. And does the FDA periodically hold meetings with industry to discuss how it's interpreting its standards at the time? 02:10PM

A. Yeah. There's meetings. There's Day at the FDA. There's an MDR conference where those issues are discussed. So most recent interpretations can be discussed not just amongst FDA and industry but against -- with multiple companies and FDA. Because it's -- sometimes it's complicated on what they would like reported beyond just what is stated in regulation. 02:10PM

Q. Has it been your experience that the FDA's interpretation of how it's going to apply its standards evolves over time?

A. I believe it has, because they have put out as recently as just a few years ago a pretty extensive guidance that explains how companies are supposed to interpret how -- their regulation. So the regulation hasn't really changed, but obviously devices have grown increasingly more complicated and they are just putting out their expectations that this is way you should interpret that. So we all have to adjust. 02:10PM 02:11PM

Q. What are some of the challenges that industries like you face with deciding how to classify an event report, an adverse event report?

A. It's -- because the regulations are written broad to cover all devices, it doesn't just say, oh, this is a dialysis catheter you reported on this particular situation. It's not that specific. It's -- it talks in generalities. It talks if it's this kind of device, this kind of incident, examples of those should be reported. So you have to do some interpretation of, okay, how does that example apply to my 02:11PM 02:11PM

particular device.

So as they have gotten more and more complicated and we get more and more data, which is good, it's increasingly more difficult to make sure that that reporting is consistent.

Q. Did one of the FDA's concerns expressed in the warning letter regarding Bard's complaint handling have to do with how the company distinguished between serious injury cases and malfunction cases with regard to a few complaints? 02:12PM

A. It did.

Q. And how many -- how many complaints did the FDA cite in the warning letter as to how they were characterized? Do you recall? 02:12PM

A. I want to say 10. 10 or 12 across the individual citations of numbers.

Q. Now, was the FDA telling the company that some of the complaints you had characterized as malfunctions should have been characterized as serious injuries? 02:13PM

A. They were.

Q. But were the complaints, regardless whether characterized as a malfunction or a serious injury, were all of those actually reported to the FDA? 02:13PM

A. If they are characterized as either one of those then they are already reported. So that's correct.

Q. So was the FDA's complaint not that you failed to report those complaints but simply how you characterized them? 02:13PM

A. Correct.
Q. And did the FDA express concern about the company not having reported another handful of complaints?
A. They did.
Q. And what did those complaints have to do with? 02:13PM
A. They were mostly related to the delivery system or the catheter that the filter sits on. So we had interpreted those, because there was no mention in the narrative of any of those where there was any sort of patient injury or issue with the filter itself, it was only the delivery system that was 02:14PM difficult to deploy. So they noted that we should have reported those where because there was no injury, we hadn't been reporting those.
Q. Mr. Modra, this jury has heard some testimony about the latest generation Bard IVC filter, the Denali. Are you 02:14PM familiar with that?
A. I am.
Q. And is it made through a different process than the earlier generation filters?
A. It is. 02:14PM
Q. And is it actually manufactured in significant part by a component supplier as opposed to Bard itself?
A. It is.
Q. Did a number of the criticisms of the FDA in the warning letter have to do with how you investigated complaint reports 02:14PM

that involve the Denali Filter because of the interaction with the component supplier?
A. They did. They objected to the fact that even though we had taken corrective actions, we didn't include that number of the document in the complaint event. 02:15PM
Q. Now, did any of the criticisms of the FDA in the warning letter have to do with a failure on Bard's part to report any event that involved a patient injury?
A. Not that I'm aware of.
Q. Now, after the issuance of the warning letter did you have meetings or discussions with the FDA? 02:15PM
A. We did. We were fortunate to have some discussions with them.
Q. And did the FDA provide feedback to the company about its reporting systems? 02:15PM
A. We did. It was great feedback.
Q. And did Bard then conduct a larger internal audit of its complaint handling systems on its own and report those findings to the FDA?
A. We did. 02:16PM
Q. Now, with regard to the points cited by the FDA in the warning letter regarding complaint handling, did any of those points affect the validity or accuracy of your internal tracking and trending that you do on events?
A. No, because we track and trend all the events whether they 02:16PM

are reportable or not based on the code that's assigned that we talked about before.
Q. Mr. Modra, in your role in BPV's Quality Department did you get an understanding of what sort of patients are indicated for Bard optional IVC filters? 02:17PM
A. I did.
Q. And did you also gain an understanding of what the purpose of an IVC filter is?
A. Yes.
Q. And generally, did you become generally familiar, if you weren't already, about how blood clots or deep vein thrombosis can turn into pulmonary embolism? 02:17PM
A. I did.
Q. And what's your understanding from your work at Bard regarding the clinical danger of pulmonary embolism? 02:17PM
A. Well they can be fatal, which is what the filter's purpose is trying to prevent.
Q. Are you aware of any action that the federal government via the surgeon general has taken with regard to the threat of pulmonary embolism? 02:18PM
A. Yes.
Q. Did you become familiar with that as a part of your work at Bard?
A. I did.
MR. NORTH: Could we pull up Exhibit 7411, please. 02:18PM

BY MR. NORTH:
Q. Are you familiar with this document?
A. Uh-huh. Yes.
Q. And what is it?
A. Surgeon general's -- it's a call to action, but it's a report on just how big a problem the pulmonary embolism is in our country. 02:18PM
Q. Have you reviewed this before?
A. I have.
Q. Is it available on the surgeon general's website? 02:18PM
A. I believe so, yes.
MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 7411.
MR. O'CONNOR: Well, objection, 803.18 and lack of foundation. 02:18PM
THE COURT: Well, overruled on 803.18. And overruled on foundation. I believe it's admissible under 803.8.
MR. NORTH: Your Honor, may we publish, please?
THE COURT: Yes.
BY MR. NORTH: 02:19PM
Q. If we could turn to Page 9, please, looking at the first paragraph, the sentence that becomes, "Estimates."
A. Yes.
Q. Begins, "Estimates."
Does the FDA provide an estimated rate of DVT and 02:19PM

pulmonary embolism in this country every year?
A. It provides the total numbers for each of those. They calculate a rate from there.
Q. And in the sentence above that does the FDA advise what the purpose of its call to arms is? 02:19PM
A. It does.
Q. If we could turn to Page 11, please.
Looking at the second paragraph, what does it say with regard to the estimated number of deaths every year from deep vein thrombosis and pulmonary embolism? 02:20PM
A. Some estimates suggest that there are more than breast cancer, AIDS, or motor vehicle incidences.
Q. If we could turn to Page 25 at Section 2, right-hand column. Right above the bolded caption.
MR. O'CONNOR: Excuse me. Are you talking about Bates Number 25 or the document number? 02:21PM
THE COURT: What page number?
MR. NORTH: 25.
MR. O'CONNOR: Which page? There's two page numbers.
MS. HELM: The exhibit Number 25. 02:21PM
MR. O'CONNOR: Okay. Thank you.
BY MR. NORTH:
Q. Does the surgeon general here discuss in this paragraph IVC filters?
A. It does. 02:21PM

Q. And what does it say regarding these devices?
A. That they act like miniature umbrellas with holes that can trap blood clots thus preventing PE without stopping the flow of blood.
Q. Turning back to the warning letter just a minute, Mr. Modra, did Bard take that warning letter seriously? 02:21PM
A. Absolutely.
Q. And what -- once the company received the letter, what actions did you take?
A. Within 15 days you have to respond fully and completely what you have done in those 15 days, reiterate what you have done prior to the warning letter and also what are you going to do to address each individual item that they have cited. 02:22PM
So you have to have that prepared and sent, delivered right to their doorstep within 15 days. 02:22PM
Q. And how much time did you personally spend to ensure adequate and appropriate responses addressing FDA's concerns in the letter?
A. The vast majority of every 15 of those days.
Q. Did Bard ultimately satisfactorily respond to FDA's concerns expressed in the warning letter? 02:22PM
A. We did.
Q. And what is a warning letter closeout letter?
A. It's the communication from FDA that says they reviewed in totality our responses, but then they have also conducted 02:23PM

follow-up visits, unannounced follow-up visits to verify on site that we have done everything we said we were going to do and they have observed the evidence for that. And then they say that the warning letter is officially closed. So they send a letter back to us. 02:23PM

MR. NORTH: Can we bring up Exhibit 5872, please.

BY MR. NORTH:

Q. Mr. Modra, do you recognize 5872?

A. I do.

Q. And what is that? 02:23PM

A. It is the warning letter closeout letter.

MR. NORTH: Your Honor, at this time we would offer 5872 as an exhibit.

MR. O'CONNOR: No objection.

THE COURT: Admitted. 02:23PM

MR. NORTH: Could we display, Your Honor?

THE COURT: You may.

BY MR. NORTH:

Q. If we could look, what does the FDA say in the first two sentences, the first paragraph there? 02:24PM

A. The Food and Drug Administration has completed their evaluation of corrective actions, which is typically that on-site audit that I talked about and then in our response. And then based on that, their assessment, it appears you have addressed all of the violations contained in the warning letter 02:24PM

and that future inspections will further assess the adequacy of the continued sustaining of that.
Q. Now, since that time has the FDA conducted any other audits or inspections of Bard Peripheral Vascular?
A. Yes. 02:24PM
Q. And did they find any violations or any issues on subsequent inspections, to your knowledge?
A. No.
Q. So to your knowledge, over the course of the years you have been involved with Bard Peripheral Vascular there have been at 02:24PM least four FDA audits of the complaint handling system?
A. At least four, yes.
Q. And has the complaint handling system changed significantly in any fashion over that period of time?
A. During what period of time? 02:25PM
Q. In the period of time that those four audits have taken place?
A. We had the procedures in place that characterized and did the same things, if anything, in addressing the warning letter items we provided additional detail. But it didn't really 02:25PM change the tracking and trending practices. It didn't track how or change how we did that. Those were already in place. So that didn't really change.
Q. Again, was there anything in the warning letter involving a failure on the part of Bard to report to the FDA any incident 02:25PM

involving a patient injury?

MR. O'CONNOR: Objection. Asked and answered.

THE COURT: Sustained.

BY MR. NORTH:

Q. Let's start talking about trending and tracking. Does the company have a policy that governs trending and tracking? 02:25PM

A. Yes.

Q. If we could bring up Exhibit 5483, please. Can you identify what this is for the record?

A. It's the procedure related to complaint trending. 02:26PM

Q. And is this maintained by the Quality Assurance Department at Bard Peripheral Vascular?

A. It's maintained by quality as well as for the use of everyone involved.

MR. NORTH: Your Honor, at this time we would offer for admission Exhibit 5483. 02:26PM

MR. O'CONNOR: No objection.

THE COURT: Admitted.

MR. NORTH: If we could display, Your Honor?

THE COURT: You may. 02:26PM

MR. NORTH: If we could turn to Page 2, Scott.

BY MR. NORTH:

Q. Does this delineate or outline what sort of trending and tracking your department does?

A. It does. 02:26PM

Q. Tell us, if you will, what some of the things are that the quality department does trend and track.
A. As it reads there, there's daily reports, weekly reports, a comprehensive monthly report where it's tracked by product family, by product line, by month by month the date the event is reported as well as failure modes. So it also goes through the rates, the device codes, so all of those. 02:27PM
Q. If we could look -- highlight Number 6 for a moment.
When you talk about rates, are you talking about rates of complications received by a company? 02:27PM
A. We are.
Q. And how frequently are those monitored?
A. At least monthly.
Q. And how do you compute those rates?
A. You take the number of reported incidences and divide it by the reported sales for that particular product family or product code itself. 02:28PM
Q. Now, do you do any tracking or trending with regard to patient outcomes or the severity of the complications?
A. We do only in such that you include MDRs as tracking and trending. But it's focused on the types of failure modes, the product lines themselves, what the reported event was. 02:28PM
Q. And what do you do with that information?
A. Well, when you track and trend it as required, you can tell if there's an increasing trend, a decreasing trend. If, for 02:28PM

instance, there's one particular month that has a lot of incidences, that might be triggered in our early warning system, as it says here, to look into that further. Is it just that people reported a lot more incidences in a particular month or was it because there was something different going on? 02:29PM

So it's important to look at it month for month on a periodic basis to compare it to the months around it to know is it increasing or decreasing.

Q. Is that information reported to management at Bard Peripheral Vascular? 02:29PM

A. It is.

Q. On a routine basis?

A. At least monthly.

Q. What is the Management Board at Bard Peripheral Vascular? What does that mean? 02:29PM

A. It consists of the heads of each of the different departments and the president. So it's his staff essentially. It's research and development, quality, regulatory, marketing sales, manufacturing. I think that's it.

Q. And does the Management Board at Bard peripheral meet on a regular basis? 02:29PM

A. Every month at least.

Q. And does the Management Board share information at these monthly meetings about adverse events that have been reported to the company? 02:29PM

A. We spend a lot of time discussing a very thick packet of analysis that typically was put together by my department and shared through me to that team.

THE COURT: We're going to break at this point, Mr. North. We'll continue at 2:45. 02:30PM

MR. NORTH: Thank you, Your Honor.

(Jury out at 2:30 p.m.)

THE COURT: Mr. North, how much longer do you have?

MR. NORTH: I think I have about 20 more minutes on direct. 02:30PM

THE COURT: All right. We'll see you in 15 minutes.

(Recess from 2:30 p.m. until 2:47 p.m.)

THE COURT: You may continue, Mr. North.

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH: 02:47PM

Q. Mr. Modra, does Bard have a policy for remedial actions?

A. Yes.

Q. What does that mean in your business, product remedial action?

A. It's the process to decide whether a particular issue could result in a product recall of some kind, either communication to customers or pulling product from the field. 02:47PM

Q. If we could bring up Exhibit 5563, please.

Do you recognize what this is?

A. Yes. 02:47PM

Q. And what is this?
A. It's the product remedial action standard.
Q. And this is the one that governs what your company does?
A. Yes.
MR. NORTH: Your Honor, I believe this may be admitted, but if not, could we tender for admission? 02:48PM
THE COURT: It's not admitted. What is your response, Mr. O'Connor?
MR. O'CONNOR: No objection.
THE COURT: Admitted. 02:48PM
MR. NORTH: May we display to the jury, Your Honor?
THE COURT: Yes.
BY MR. NORTH:
Q. Is this sometimes nicknamed internally the R002 policy?
A. It is. 02:48PM
Q. How does Bard decide whether remedial action must be taken?
A. We conduct an investigation into the root cause of what the issue is, and then you pair that -- you take that information and you have a medical director assess the severity, potential severity of that issue and the breadth of that issue and you 02:48PM match that with the rate of occurrence of the particular issue, and in a chart it determines what additional action you have to take.
Q. If we could turn to Page 12, please.
Tell us what this matrix means. 02:49PM

A. That's the chart I was referring to that it takes the severity along the bottom and then the rate of occurrence, worst-case occurrence on the left-hand side. And when you match those two up, it gives you different regions with which the actions are required below that. 02:49PM

Q. How are occurrences determined?

A. They are worst-case scenarios for the particular issue. So if it's related to a particular month, you would take the units made in that month, or -- so it's the observed and the potential units related to that issue. 02:49PM

Q. And how is severity determined?

A. By the medical director. They review literature. They are aware of the procedures and then they make an assessment called an HHE, Health Hazard Evaluation. And that is put into a bucket, either catastrophic, critical, moderate, marginal, or negligible. 02:50PM

Q. On the second chart underneath there, you have action levels. How do you determine those action levels?

A. When you have, let's say, a marginal, which is a Number 2 severity, paired with something that happens 1 in 5000, a Number 4, you have the yellow category. And then that says potentially acceptable, we have to review that meaning you have to assess the investigation itself and the actual incidences and the potential effect on regulation if you are evaluating that. And then you take the appropriate action. 02:50PM 02:50PM

Q. And what does it mean by Division PAT?
A. That's the Management Board, essentially, or some members of that that have to review that and then determine whether additional action is required. They can approve that.
Q. Now, you were talking to us earlier -- 02:50PM
MR. NORTH: You can take that down now.
BY MR. NORTH:
Q. Let me ask you this, Mr. Modra: Over the course of your seven years at Bard using this R002 policy for product remedial action, has Bard ever internally determined that the Eclipse 02:51PM
Filter is unsafe?
A. No.
Q. And using that same policy, has Bard ever determined that the Eclipse Filter should be recalled based on internal company policies? 02:51PM
MR. O'CONNOR: Objection. Irrelevant, Your Honor. May we approach?
THE COURT: Yes. If you want to stand up, Ladies and Gentlemen.
(Discussion was had at sidebar out of the hearing of 02:51PM
the jury:)
MR. O'CONNOR: I thought we talked about this earlier today that we could not discuss recall whether they recalled something or not.
MR. NORTH: Certainly no claim for -- 02:52PM

THE COURT: I don't know what you are talking about.

MR. O'CONNOR: We don't have any claim for recall. That's why you have made some rulings the way that you did.

THE COURT: Recall of Recovery. I said that last night in my order. What does that got to do with whether the problems with the Eclipse ever got into the severity range that would cause the -- 02:52PM

MR. O'CONNOR: Maybe I misunderstood the extent, but I still think it's irrelevant. I mean, non-enforcement is different than enforcement. And whether they had this recall or not, I think that causes this jury to speculate on, once again, what the FDA knew or didn't know about this device. 02:52PM

MR. CLARK: We also aren't making a claim for failure to recall.

MR. NORTH: Your Honor, first of all, this question was not posed in terms of the FDA recalling but whether their internal safety processes of this policy and others triggered an internal decision that remedial action was necessary. And I believe that is a fair question as to the reasonableness of their conduct. 02:52PM 02:53PM

I also believe the FDA decision, because that's coming down in about 10 minutes, I will ask a question about that, I think the Court has ruled on that already. Certainly this is not even determining what the FDA, this is corporate decision making. 02:53PM

THE COURT: Anything further?

All right. I'm going to overrule the relevancy objection. I think it's relevant.

(In open court.)

THE COURT: Thank you. 02:53PM

The objection is overruled.

BY MR. NORTH:

Q. Let me phrase the question again, Mr. Modra. Pursuant to this R002 policy or any other internal policies the company has, has Bard ever determined that the Eclipse Filter should be 02:53PM recalled?

A. No.

Q. Now, as a part of Bard's tracking and trending, what does it use for the numerator in coming up with projected rates of reporting complications? 02:54PM

A. The reported events.

Q. And then what does it use for the denominator in determining -- calculating that rate?

A. Sales numbers.

Q. Why don't -- why do you use sales numbers, the number of 02:54PM devices sold? Why don't you use the actual number of devices implanted in patients?

A. One, it's we can't get the number of devices actually implanted; and two, the sales numbers are reliable. We can get them for each month and so that's why. 02:54PM

Q. But don't you have concern that using sales numbers as the denominator in calculating rates might artificially depress the ultimate rate because not all filters that are sold are actually implanted?
A. True. But the sales number, in my experience in these products, is close because they are technical, used in very specific situations. They are typically expensive. So it's -- the hospitals, in my experience, don't keep a lot of them on the shelf. And anything that is returned we take out of the sales number each month. 02:55PM
So that's why I would say it's close but not significantly different than the rate that we're getting reported.
Q. Now, as a part of forming the -- or performing these rate calculations, does the company utilize adverse events in coming up with a number regardless whether characterized as a serious injury or as a malfunction? 02:55PM
A. We do. The rates are based on the failure mode and the code itself. And the code is applied to all complaints, so it's not whether it's reportable or not. That's a subset. 02:56PM
It's -- the tracking and trending is done on complaints.
Q. Now, as a part of this rate calculation that Bard trends and tracks, do you do so or use events even, or regardless whether they are actually reported to the FDA?
A. Yes. 02:56PM

Q. Now, does Bard perform all of these sorts of rate calculations we have been talking about generally with regard to IVC filters?
A. Yes.
Q. Do they do so with regard to fracture, migration, perforation, and tilt among other complication modes? 02:56PM
A. Yes.
Q. If we could bring up Exhibit 5874, please.
Are you familiar with this document?
A. I am. 02:57PM
Q. Tell us what this is, please.
A. It's a summary of those complications that you mentioned with a few others for each of the filter families from, looks like, from the date of their launch to December 16.
Q. Is this the sort of calculation or tracking that Bard performs with regard to filters on a regular basis? 02:57PM
A. Yes.
Q. And are these tracking and trending calculations made by the company, approximately how often are they performed?
A. These are calculated each month and then on an ad hoc basis in addition. 02:57PM
Q. And are these rate calculations maintained in the ordinary course of Bard's business?
A. Yes.
MR. NORTH: And, Your Honor, at this time we would 02:58PM

tender Exhibit 5874 into evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

MR. NORTH: May we display, Your Honor?

THE COURT: You may. 02:58PM

MR. NORTH: Could we somehow blow this up a little.

Let's look, if we could, just through halfway, through Denali. Right there. Yeah.

BY MR. NORTH:

Q. Tell us what this is depicting here. Is it showing, first of all, the rates through December of 2016? 02:58PM

A. It says sales through December '16, and it's not the rates it's the numerator and denominator separately.

Q. And as of December 2016, how many Eclipse Filters had been sold? 02:59PM

A. 66,563.

Q. And how many reports of fracture with the Eclipse out of that 66,563 sold have there been?

A. 110.

Q. How many migrations would there have been? 02:59PM

A. 50.

Q. Now, migration here, would that include both migrations in the cephalad or upward direction and migrations in the downward or cranial -- I mean caudal direction?

A. It includes all reports of migration. 02:59PM

Q. And how many perforations had been reported as of December of 2016?
A. 101.
Q. And then look at the very bottom. How many tilts would have been reported as of then? 02:59PM
A. 127.
Q. And then further on the right, does it actually compute the rate?
A. It does.
Q. So based on sales through 2016, what was the rate of 03:00PM reported fractures for the Eclipse Filter?
A. .17 percent.
Q. What was the rate of reported migrations?
A. .08 percent.
Q. What was the rate for perforation? 03:00PM
A. .15 percent.
Q. And what was the rate for reports that Bard had received of tilt?
A. .19 percent.
MR. NORTH: Now, if we could bring down the G2 rate 03:00PM column, please.
BY MR. NORTH:
Q. Was the reported rate of fracture with regard to the Eclipse an improvement over the reported rate of fracture with the G2? 03:01PM

A. It was.
Q. And what about with migration. It appears it was twice as or half as much for Eclipse as for the G2. Is that correct?
A. That's correct.
Q. And with regard to perforation, were the reported rate of perforations with regard to the Eclipse an improvement over the G2? 03:01PM
A. It was.
Q. And lastly, what about tilt?
A. That was as well. 03:01PM
Q. Based upon the data that Bard has been able to collect, does it appear that Bard was successful in reducing the incidence of fractures in the Eclipse Filter?
A. It does.
Q. Does it appear that Bard was successful in reducing the rate of migrations? 03:02PM
A. It does.
Q. Now, Mr. Modra, these aren't perfect calculations as to what the rate is in the real world, are they?
A. No. 03:02PM
Q. And you would agree that not all 66,000 filters sold, Eclipse Filters sold as of that date were actually implanted in patients?
A. No. No.
Q. But as you have indicated earlier, would you expect that 03:02PM

most of them were?
A. I would expect so, yes.
Q. In your experience with Bard, do you believe that these rates would include any adverse event that the company had heard about? 03:02PM
A. Yes.
Q. Including all complications reported in the medical literature?
A. Yes.
Q. All complications reported by doctors? 03:02PM
A. Yes.
Q. All complications overheard by, received from, sales representatives in the field?
A. Yes.
Q. And all complications reported to the hotline in Covington? 03:03PM
A. Yes.
Q. Would this even include all reports of complications discussed at SIR conferences?
A. They would.
Q. In fact, Bard peripheral sends delegates or people to attend and monitor the Society of Interventional Radiologists annual conferences, correct? 03:03PM
A. Correct.
Q. And there are a number of presentations there?
A. Yes. 03:03PM

Q. So would the employees that have gone and visited that come back and report to the Quality Assurance Department any adverse events they had learned about in those presentations?
A. They would.
Q. Mr. Modra, does Bard Peripheral Vascular make every effort to find out and investigate every report of fracture, migration, perforation, and tilt regarding its filters? 03:03PM
A. I believe we do.
Q. Now, did your department consistently track these events throughout the time you were at Bard Peripheral? 03:04PM
A. They did.
Q. And does it continue to do so?
A. Yes, it does.
Q. And, in fact, even though you have this other position your office is still in the same building as Bard Peripheral Vascular, correct? 03:04PM
A. My phone line is still here.
Q. Over your years with Bard Peripheral Vascular and your work with these IVC filters, Mr. Modra, to your knowledge, has the FDA ever suggested or said to Bard that the Eclipse Filter needed to be recalled? 03:05PM
A. No.
Q. Has, at any point, the FDA, to your knowledge, during your years with the company, ever suggested that the warnings or the IFU with regard to the Eclipse needed to be changed in any way? 03:05PM

A. No.

MR. NORTH: Thank you. That's all the questions I have.

THE COURT: Cross-examination.

CROSS-EXAMINATION 03:05PM

BY MR. O'CONNOR:

Q. Hello, Mr. Modra. How are you?

A. Fine. Thank you.

Q. Let's just talk about something you just talked about. You do not know how many filters of any kind that Recovery, G2, 03:05PM G2X, or Eclipse have been implanted, correct?

A. Correct.

Q. And you do know that the Eclipse was only on the market from January 2010 to 2011. True?

A. I don't know the date that it was not on the market. The 03:05PM Eclipse?

Q. Yes. Eventually the Meridian took over the Eclipse, right?

A. Correct.

Q. And the Eclipse, Bard stopped selling the Eclipse, correct?

A. We did. 03:06PM

Q. And you do know that the only complaints that you receive are those that are reported. True?

A. That's correct.

Q. You also know that there are complaints that are underreported, correct? 03:06PM

A. Yes.
Q. That's a problem with reporting. There are many that don't ever make it. There's a problem with underreporting?
A. There are some. That's correct.
Q. And you know who Dr. Ciavarella was? 03:06PM
A. Yes.
Q. And are you aware that he testified that he believes that maybe only 1 to 5 percent of actual failures or problems with filters are reported?
A. I wasn't aware that he testified that. 03:06PM
Q. You don't have any reason to dispute that he testified to that?
A. In my experience it's not 1 to 5 percent.
Q. Now, in terms of underreporting, there are also patients out there who may have a failed Eclipse who don't know it, 03:07PM correct?
A. True.
Q. And it could be a fracture that is in a location that may be dangerous but they don't have symptoms, so a patient has no reason to report that to a doctor, correct? 03:07PM
A. True.
Q. And you simply don't know how many patients are walking out there with failed Bard filters. Fair?
A. True.
MR. O'CONNOR: Now let's go to Exhibit 1680, Gay. 03:07PM

May we publish this to the jury, Your Honor?

THE COURT: Yes.

BY MR. O'CONNOR:

Q. Mr. Modra, this is the warning letter that Bard received on January 15, 2015, correct? 03:08PM

A. Correct.

Q. And this was an inspection by the FDA, correct?

A. Prior to this there was an inspection, correct.

Q. An inspection that was conducted by an FDA investigator. True? 03:08PM

A. True.

Q. And what the warning letter was, it addressed violations. Correct?

A. That's what it says. Correct.

Q. And, in fact, the FDA found violations. Is that right? 03:08PM

A. They cited them, correct.

MR. O'CONNOR: Gay, let's go to Page 4.

BY MR. O'CONNOR:

Q. The FDA found that you, in your procedures in Tempe, failed to establish procedures for receiving, reviewing, and 03:08PM evaluating complaints. Is that correct?

A. Yes. That's what they stated and that's standard language that they would use to cite things.

Q. That's what it says in this letter that's a warning letter, correct? 03:09PM

A. That's what it says, correct.
Q. And it's an official document from the FDA. True?
A. It is.
Q. And also you were also -- the FDA also found that Bard failed to not have adequate instructions for ensuring that complaints involving a device or device component provided by a supplier are adequately evaluated for root cause of the alleged device failure. Do you see where that is? 03:09PM
A. I do.
Q. And root cause is an important part of post-market surveillance. True? 03:09PM
A. Not just post-market surveillance, but day-to-day activities. Correct.
Q. When you find out a filter has failed, you are supposed to do a root cause analysis, correct? 03:09PM
A. An investigation root cause analysis.
Q. And that is an important piece of not only developing the filter but surveillance following up with the filter after it's on the market. True?
A. Correct. 03:10PM
Q. I mean, you know that there are people out there that rely on Bard to accurately report complaints, correct?
A. Yes.
Q. And doctors are out there who have to make risk/benefit decisions about filters. True? 03:10PM

A. Yes, they do.
Q. And one thing a doctor must be able to rely on is that a company like Bard has done an adequate root cause analysis of failures that it discovers. Fair?
A. True. 03:10PM
Q. Now, you -- Bard was also found to have violated the requirement on how it characterized complaints; malfunctions versus serious injury. True?
A. Correct.
Q. For example, one of the complaints that Bard found involved 03:10PM an Eclipse Filter that concerned a detached filter limb which resulted in pericardial effusion and cardiac catheterization. Right?
A. Yes.
Q. Bard said that was a malfunction; FDA said that was a 03:11PM serious injury. Correct?
A. I believe that was it, yes.
Q. And going on, G2 Express, for example, the next one, a patient had a broken filter and surgical intervention. And again, the FDA said that's a serious injury. That is not a 03:11PM malfunction. Right?
A. Yes.
Q. And when the jury receives, as they can look at this paragraph, these paragraphs on Page 4 and 5, and they can see examples of what Bard was calling malfunctions that should have 03:11PM

been serious injuries. True?
A. True.
Q. And it's important that Bard is accurate when it reviews a complaint and refers to it either as a serious injury or a malfunction, right? 03:12PM
A. Yes.
Q. Because you know that doctors are going to rely on your reporting to the MAUDE database. Right?
A. I don't know that to be the fact that they are going to rely on MAUDE. 03:12PM
Q. You have an obligation to be accurate, correct?
A. Yes.
Q. And you at Bard need to know the difference between what is a serious injury and what is a malfunction. True?
A. Yes. 03:12PM
Q. And then you were also -- the FDA also found that there were complaints that weren't adequately reported that involved procedures that were not successful, and that's in Paragraph C. Right?
A. Yes. 03:12PM
Q. In other words, when a filter fails, and the patient requires surgery because of that failure, and that's reported to Bard, Bard needs to report that fact. True?
A. It didn't say that the filters were failing in this incident. It was just that they had difficulty retrieving 03:13PM

them.
Q. Fair enough. But you understand that difficult retrievals can occur because of failed filters, right?
A. Yes. But normal operating procedures with normal operating filters would require retrieval as well. 03:13PM
Q. But in any event, this, again, was an example that the FDA found was a violation of regulations. True?
A. They cited those -- out of those 10 patients, the two that were resulting in injury to the patient were filed.
Q. Now, the Bard inspection that occurred, that led to this letter, did not look at the design of your filters, did it? 03:13PM
A. It did.
Q. They didn't go -- excuse me -- the FDA does not examine and inspect devices.
A. They went through the design file, and I defended it personally to the inspector. 03:14PM
Q. They didn't inspect the actual filters. True?
A. No.
Q. And FDA inspections are a form of post-market surveillance. True? 03:14PM
A. Ongoing surveillance, correct.
Q. Well, excuse me. It happens during the post-market period, correct?
A. Not always. It happens during submissions, regulatory submissions of new products prior the release of products. 03:14PM

Q. I think here's the point: The 510(k) clearance process is handled in the division of cardiovascular devices which is located in Silver Springs, Maryland. Is that right?
A. I believe so, yes.
Q. This inspection, this warning letter, came from the Los Angeles District Office of Compliance in Irvine, California. True? 03:14PM
A. Yes.
Q. You had mentioned that there were other issues about the deployment process. Do you recall that? 03:15PM
A. I do.
Q. And you are familiar with the device?
A. I am.
MR. O'CONNOR: Your Honor, may I show Mr. Modra an exemplar of a device? 03:15PM
THE COURT: Yes.
BY MR. O'CONNOR:
Q. Mr. Modra, you are familiar with how the devices are packaged, correct?
A. Correct. 03:15PM
Q. And they are delivered to hospitals in this type of package. Right?
A. Correct.
Q. And they are also in -- the deployment instrument is in this type of a container, right? 03:15PM

A. Correct.
Q. And you understand that there's paperwork inside this box, correct?
A. There is.
Q. And what happens is when -- before it ever gets to the operating room, you understand that somebody will open this package and get it into the sterilized room. Is that right? 03:15PM
A. Correct.
Q. That process of opening the package is done before the procedure is ever performed on a patient. True? 03:16PM
A. It would have to be, correct.
Q. And when it gets to sterilization the concern is was this unwrapped sometime or was there some risk of sterilization, for example, before it got to the procedure room?
A. Some risk of sterilization? I'm not familiar. 03:16PM
Q. Lack of sterilization I thought you talked about was one of the issues.
A. Well --
Q. The deployment is a process that happens after the device is removed from the package, correct? 03:16PM
A. It has to be, correct.
Q. And the device is brought to the room and given to the doctor, correct?
A. Correct. And I don't know at what point the handoff between their support staff and them takes place. 03:16PM

THE COURT: Mr. O'Connor, does that have an exhibit number?

MR. O'CONNOR: No, it doesn't. Just for the record, Your Honor, it's an exemplar G2X Vena Cava Filter in a box, in the deployment system. Is that right? 03:16PM

THE WITNESS: I can't see it from here.

MR. O'CONNOR: May I approach?

THE COURT: I will stipulate that it is.

MR. O'CONNOR: Gay, could we go to Exhibit 4519. I believe this is in evidence, Your Honor. 03:17PM

THE COURT: Yes.

MR. O'CONNOR: May I publish?

THE COURT: You may.

MR. O'CONNOR: And Gay, just go to Page --

BY MR. O'CONNOR: 03:17PM

Q. Well, first of all, Mr. Modra, you recognize this is the monthly management report, correct?

A. It looks similar to a report I have been familiar with later on. But this was before I arrived at BPV.

Q. This is dated August 9, 2010? 03:17PM

A. Right. I arrived there in March of 2011.

Q. Thank you. So you arrived after the Eclipse had been put on the market?

A. Yes.

Q. And in any event, in this monthly report, we talked about 03:18PM

these last time you were here.

MR. O'CONNOR: Gay, if you go to Page 12, please.

BY MR. O'CONNOR:

Q. And when the jury sees 4519, they will know that there are parts of the report that have to do with the business of Bard up front, correct, how sales are going and how products are doing on the market. That's the first few pages. You looked at that before? 03:18PM

A. I don't recall that.

Q. For example -- 03:18PM

MR. O'CONNOR: Let's go to Page 5, Gay.

BY MR. O'CONNOR:

Q. As you can see, for example, one page of this report deals with key product line sales per day. Do you see that?

A. Yes. 03:18PM

Q. And then as you get to the end of the report, go to Page 12. That's where adverse events that are reported to Bard are included in the report based upon the information that comes from your department. True?

A. That's where they would be reported, correct. 03:19PM

Q. And you have seen this format. We talked about this when you first came two weeks ago. Do you recall that?

A. Yes.

Q. Thank you.

MR. O'CONNOR: Gay, if you could go to Exhibit 4565. 03:19PM

And, Your Honor, I believe this is in evidence. This is the 1006 summary.

THE COURT: Yes, it is.

BY MR. O'CONNOR:

Q. Mr. Modra, when I had talked to you two weeks ago, we talked about the event descriptions that developed in the complaint process. Do you recall that discussion? 03:20PM

A. Yes.

Q. And so --

MR. O'CONNOR: May I publish this, Your Honor? 03:20PM

THE COURT: Yes.

BY MR. O'CONNOR:

Q. This is Exhibit 4565. And what we have done here is we have done failures reported to Bard. That's in complaints that have come to Bard between the period of 2003 and 2015. Do you see that? 03:20PM

A. I see it at the top.

Q. And we have summarized and put in there examples, we have the total failures are 345, for the period 2003 to 2015. And then for the jury to understand, we can go through this. And on the first page, on Page 1, we have put 10 examples of total failures of -- 10 examples of Recovery Filter failures. Do you see that? 03:21PM

A. I see it.

Q. And so we have the date on the left. We have the product 03:21PM

on the next column. We have the primary FDA code which you have talked about and then other information including the event description. Do you see that?
A. I see the column heading, correct.
Q. And then on Page 2, what we have done following the event descriptions that were provided by you at Bard, we have given 10 examples of G2 Filter failures. Do you see that? 03:21PM
MR. NORTH: Your Honor, I'm going to object. I think Mr. O'Connor is just testifying.
THE COURT: Overruled. 03:22PM
BY MR. O'CONNOR:
Q. Do you see that, sir?
A. I see that. I don't know where this report had originally come from because it doesn't look like a report I put together before. 03:22PM
Q. No, it has been put together and we have admitted it in evidence. And I'm just having you take a look at it. This is the type of information you and I talked about two weeks ago, the format of how you use event description.
A. Sure. 03:22PM
MR. O'CONNOR: If we go to Page 3, Gay, so I can show Mr. Modra we have 10 examples of G2X Filter failures. And then Page 4 we have 10 examples of Eclipse failures.
BY MR. O'CONNOR:
Q. And then at the last page, what we have, and the jury can 03:22PM

see, is that we have broken down by types of failures for each of the filters in terms of fractures, perforations, migrations, and tilts. Do you see that?
A. I see it.
Q. And that's something Bard has been able to do, too, is to categorize complaints by filter, by failure. There's a number of things that you can do with your system, your TrackWise system. Fair? 03:23PM
A. There are a number of things, but I don't know the validity of these numbers here, though, because the people trained in the procedure didn't do that for me. 03:23PM
Q. All right. Now, when you talk about tracking and trending, you agree that there are limitations to be accurate in your tracking and trending at Bard. Correct?
A. Correct. 03:24PM
Q. Underreporting is one limitation. True?
A. To a small extent, correct.
Q. You just don't know the extent, though, do you?
A. Based on experience, I have a pretty good guess.
Q. Well, I'm not looking for guesses here. But you also don't know, and nobody at Bard knows, how many patients are out there who have filters that have failed; tilted, perforated, fractured, or embolized to hearts or lungs that simply don't know it. Correct? 03:24PM
A. We don't know it. 03:24PM

Q. And it's only when a patient reports or sees a doctor and the doctor learns about the problem that it may be reported to Bard. True?
A. True.
Q. And even then there are times that you don't know at Bard, that even doctors in the medical community aren't reporting everything they see. Fair? 03:25PM
A. True. But the more severe an event the more likely they are to report it.
Q. I understand. One issue about asymptomatic is a piece of a filter can be in a place that's dangerous to the patient and the patient may not know about it. True? 03:25PM
A. And if it's asymptomatic, it is not really causing any issue, either.
Q. But you understand there's diseases that are asymptomatic but they can be potentially fatal. Correct? 03:25PM
A. I understand that.
Q. And that's the problem with failed filters and fragments. They can be in a patient and be located in a dangerous position or location that could be potentially fatal or seriously harmful to a patient. You understand that, don't you? 03:25PM
A. I understand that. And they could be in a non-harmful location as well.
Q. But one thing you have to be concerned about is the patients that have those that don't know about them. True? 03:26PM

A. I'm concerned about all of them.
Q. Thank you.
THE COURT: Redirect?
MR. O'CONNOR: I have one more question.
Gay, would you put up Exhibit 2217? Go to the next page, Gay. 03:26PM
BY MR. O'CONNOR:
Q. Mr. Modra, do you recognize this document?
A. I do.
Q. It's to you from Judy Ludwig, and it's dated January 23, 2015? 03:26PM
A. It is.
Q. And it's an IVC filter retrospective review?
A. Correct.
MR. O'CONNOR: May I publish? 03:27PM
THE COURT: It's not admitted yet.
MR. O'CONNOR: I offer it into evidence, Your Honor. I apologize.
MR. NORTH: No objection, Your Honor.
THE COURT: Admitted. 03:27PM
BY MR. O'CONNOR:
Q. Do you recall how many --
THE COURT: Do you want it published now?
MR. O'CONNOR: Yes, please, Your Honor.
THE COURT: All right. You may. 03:27PM

BY MR. O'CONNOR:
Q. And Mr. Modra, it says that the results of the retrospective review identified a total of 274 complaint records which meet the definitions of malfunction and serious injury. Do you see that? 03:27PM
A. I do.
Q. That's dated January 23, 2015?
A. That's correct.
MR. O'CONNOR: No more questions.
THE COURT: All right. Redirect? 03:28PM
MR. NORTH: Yes, Your Honor.
Could we bring that same exhibit up, 2217?
Your Honor, can we publish?
THE COURT: You may.
MR. NORTH: Could we go to the second page? 03:28PM

REDIRECT EXAMINATION

BY MR. NORTH:
Q. Mr. Modra, after this retrospective review was conducted, did you have discussions with the FDA about the retrospective review? 03:28PM
A. We did.
Q. And did you, based on those discussions, make any determination as to whether you had been overly aggressive in how you recharacterized those events?
A. We did. The original review was done without input from 03:28PM

FDA. We had to kind of interpret what they were saying in their observation. So we overcorrected.

MR. O'CONNOR: Objection. Hearsay, Your Honor.

THE COURT: Overruled.

THE WITNESS: And then we prepared this memo to summarize it. But then after discussions with FDA that I was involved in directly over the phone, they said that you were overcorrected. You had done too much in over-interpreting that and actually 93 percent of these were really not reportable in that manner to them. 03:28PM 03:29PM

So we have a subsequent memo that says that, but to be conservative, we left them as reported with FDA.

BY MR. NORTH:

Q. But regardless how they were characterized as malfunction or serious injury, had they at all times been reported to the agency? 03:29PM

A. They were reported, or I mean tracked and trended regardless of whether they were reported or not. So this didn't really have any impact on that.

Q. Well, if something was simply just mischaracterized as a malfunction versus a serious injury, would it still have been reported to the FDA? 03:29PM

A. Yes.

Q. I mean, are malfunctions -- if you characterize an event as a malfunction, does that go to the FDA? 03:29PM

A. Yes, it does.
Q. Now, you also mentioned, I believe, or did you say that during the FDA inspections in 2015 they also reviewed design documents regarding Bard's IVC filters?
A. They did. 03:30PM
MR. NORTH: Thank you, sir. That's all I have.
THE COURT: All right. Thanks. You can step down.
MR. NORTH: Your Honor, at this time the defendants would rest.
THE COURT: Okay. Counsel, would you approach for a minute, please? 03:30PM
You can stand up, Ladies and Gentlemen.
(Discussion was had at sidebar out of the hearing of the jury:)
THE COURT: Do you have any rebuttal evidence you want to present? 03:30PM
MR. CLARK: We do, Your Honor. And we also have a Rule 50 motion that we can take up at a different time.
THE COURT: A Rule 50 motion on --
MR. CLARK: Mitigation of damages and assumption of risk. 03:30PM
THE COURT: Let's deem that as made and we'll hear argument when we're not keeping the jury waiting.
MR. CLARK: Your Honor, we would like to play the eight and-a-half minute deposition of Dr. Moritz. Mindful of 03:31PM

the Court's admonition that that should not be cumulative. We think it is both proper rebuttal and not cumulative because it deals with a little bit of --

THE COURT: Tell me who he is why this is an issue.

MR. CLARK: He is an expert that formerly had been retained by Bard and withdrawn. So he, like Dr. Rogers, is subject to your order that could be used but you are going to instruct the jury neither party is offering him. And obviously it could not be cumulative and we do not think it is cumulative. 03:31PM

THE COURT: What is it he's going to cover?

MR. CLARK: He's going to cover primarily a little bit about that would be responsive to Dr. Trerotola about the type of information a physician would like to get and why that's important, very little about that. Most of what he would cover is there are risks to patients who have fragments lodged in the pulmonary artery, and there are other risks. I don't think anybody has really developed the type of risk he talked about in terms of infection. He does talk about thrombosis but one of seven or eight things he mentions. In fairness, he did say it's a small risk. But I think that's important particularly after Dr. Stein said she's not in danger. I would tell my patients there's nothing to worry about. 03:31PM 03:32PM

MS. HELM: Your Honor, we disagree that this is in rebuttal to anything, particularly to anything that Dr. 03:32PM

Trerotola testified about. And, in fact, it is -- we don't believe the plaintiffs have made the showing required under your order, which is Docket 10382. And I have a copy for you.

THE COURT: I remember the order.

MS. HELM: In the fact that your order specifically said that they must make the showing that no other expert of similar qualifications is available or that that unavailable expert has some unique testimony to contribute. 03:32PM

I have gone through Dr. Moritz's testimony, and I can actually refer to page and line numbers of the transcript where Dr. Hurst and Dr. Muehrcke and their cross of Dr. Stein covered virtually everything in this transcript. He talks about physician expectations which were covered at length by Dr. Hurst and Dr. Muehrcke. He talks about articles which were covered, the Nicholson article. He talks about articles that they used to cross-examine Dr. Stein. He talks about a description of the pulmonary artery which was described by Muehrcke, Dr. Hurst. He talks about physician expectations, which Dr. Hurst testified about at length. 03:33PM 03:33PM

And then he talks about Ms. Jones, including claims that they have withdrawn in the case, that she needs to have continued follow-up and monitoring by a doctor and the complications of the strut in her pulmonary artery which have been covered at length. There's simply nothing new or unique in his testimony. There's nothing in it that rebuts Dr. 03:33PM 03:34PM

Trerotola. And we don't believe that they can make or have made the showing as required by your order.

THE COURT: Okay.

MR. CLARK: I think we do have to treat him similar to the way Dr. Trerotola was treated. Since he's not being retained as an expert, essentially is a neutral party who would come in and give some commentary on some of these issues. And I don't think that any of the experts have covered things like infection or bleeding, corrosion. So those are other symptoms she's at risk for. 03:34PM

Again, it's a small point, short point, but it's to rebut this notion there's nothing really to worry about and doctors have thrown away the IFU.

THE COURT: Do you have another expert who is available to testify at this point? 03:34PM

MR. CLARK: No, Your Honor.

THE COURT: What about Ms. Helm's point that he describes damages categories you have withdrawn?

MR. CLARK: I think we cannot take that out of the run. We would be open to the idea with an instruction saying there's no claim made for that monitoring component. 03:35PM

THE COURT: I understand that this is stuff that's previously been covered but this is a rebuttal case. And it's in response to what defendants have presented. I think that makes it relevant and unique in that respect. There isn't 03:35PM

another doctor available so I am going to permit plaintiffs to play it.

Let's hold off on the issue of me instructing the jury on damages because we're about to talk about a damages instruction and if you think that we need to include something in there that specifically addresses this doctor, you can certainly raise it. And I'm saying that to defendants. 03:35PM

MR. CLARK: And one thing, we did have an agreed upon summary. I would like to track the Rogers one says Dr. Moritz is not being presented as an expert witness by either party like we did for Dr. Rogers. 03:35PM

MS. HELM: Actually, I think this is a little different in the fact that Dr. Rogers testified specifically about an article that he wrote. He did not provide any specific testimony about Ms. Jones. In this case -- 03:36PM

THE COURT: Well, so do you want him to be presented to the jury as an expert?

MS. HELM: Well, I don't want him presented as an expert on the behalf of the defendants.

MR. CLARK: But he was. 03:36PM

THE COURT: Do you want him to be presented as an expert on behalf of the plaintiff?

MS. HELM: I guess not. You talked me into it, Your Honor.

(In open court.) 03:36PM

THE COURT: Thank you, Ladies and Gentlemen.

All right. You have some brief rebuttal evidence, Mr. Clark?

MR. CLARK: Your Honor, very briefly the plaintiff would call Dr. Mark Moritz via video deposition. May I be permitted to read his background? 03:36PM

THE COURT: Yes, you may.

MR. CLARK: Mark Moritz is a medical doctor specializing in the area of vascular surgery. He has examined Mrs. Jones's medical records and has opinions concerning the filter fracture lodged in the middle lobe of her right pulmonary artery. Dr. Moritz is not presented as an expert witness by either party. 03:36PM

THE COURT: All right. Thank you. You can play that.

(Video testimony of Mark Moritz, M.D. was played in open court.) 03:37PM

MR. O'CONNOR: Plaintiff rests, Your Honor.

THE COURT: All right. Ladies and Gentlemen, that's the end of the evidence. So what we are going to do is break for the day. We'll start at 9:00. I will give you some instructions then we'll hear the closing arguments by the lawyers, and you should have the case for deliberation before the lunch hour tomorrow. 03:46PM

So we will excuse you. Reminding you not to do any research or discuss the case. And we'll see you in the 03:46PM

morning.

(Jury out at 3:46 p.m.)

THE COURT: Please be seated.

As of now, plaintiff has used 27 hours and 47 minutes. The defendants used 23 hours and 46 minutes. And I don't have my mic on. Did you all hear that? 03:47PM

Let's hear the Rule 50 motion you wish to make, Mr. Clark.

MR. CLARK: Thank you, Your Honor.

Your Honor, I was informed that the assumption of the risk charge will be withdrawn, so we don't have to take that up. 03:47PM

THE COURT: Okay.

MR. CLARK: That narrows the issue to whether there is evidence sufficient -- legally sufficient evidence under Rule 50 to support a charge to the jury on mitigation of damages. And, Your Honor, we do not think that there has been any proof about mitigation of damages let alone that any such mitigation effort would have been successful. I looked through Mrs. Jones's testimony, and really, the closest we come was some questions about did you ever follow up and go to the doctor. And Ms. Helm asked her some questions about going to Memorial in 2016 after the filter was removed and what they told her about the filter. And essentially the testimony was that the filter is in a safe place. 03:47PM 03:48PM 03:48PM

So I don't really understand how going to Dr. Cooper or any other type of mitigation would support that instruction in this particular case. They would have to prove that there was some type of appropriate mitigation that could have been done, which we do not think has been shown under these facts. 03:48PM

And more importantly, that had that effort been undertaken it would have translated into some type of effect, some type of cognizable reduction in her damages. And given that her primary damages in this case are the mental anxiety and the stress and the fear of what could happen with this 03:49PM filter, we don't think there's been any evidence to suggest to her -- or to the jury in this case that it -- that she needed to do something to mitigate her damages.

So it's really just a straight lack of evidence argument, Your Honor. 03:49PM

THE COURT: Okay. Thank you. Defense counsel.

MS. HELM: I apologize, Your Honor. I'm allergic to Arizona, I think.

Your Honor, Ms. Jones' testimony actually was that she is worried about the filter and that she worries about it 03:49PM constantly. And she testified, I asked her specifically, you haven't done anything about that. You have not been to any doctor to check on the strut, have you? And her answer was, no I haven't.

So she has come before the Court, and they are making 03:50PM

a claim, their primary claim is for emotional damages for worry. And Ms. Jones herself testified that she hasn't done anything to, in fact, mitigate that worry.

The prior testimony before that was that she was going to go to a doctor to determine whether she had anything to worry about and, in fact, she didn't do that and she admitted she didn't do it. 03:50PM

So contrary to Mr. Clark's assertion, her own testimony shows that she has failed to address her emotional distress claim, her emotional damages claim, by seeking medical attention which everyone agrees would give her an answer. 03:50PM

So that alone should be sufficient evidence to get past the Rule 50 motion. And again, we are not seeking mitigation on her past pain and suffering claim or her possible future pain and suffering claim but on her emotional damages claim. 03:51PM

THE COURT: All right. Mr. Clark.

MR. CLARK: Yes, Your Honor.

I would take issue with Ms. Helm's statement that everyone agrees that seeing a doctor would alleviate her concerns. I think the testimony was that she was going to go see Dr. Cooper, who is a physician in Savannah, Georgia. She did not. But there has been no testimony or evidence of any sort establishing what Dr. Cooper would have told her had she gone to see him. 03:51PM 03:51PM

So what we're left with, Judge, is that we would be asking the jury to essentially speculate that if she had gone to a doctor that doctor would have given her some comfort that this is nothing to worry about somehow would have allayed her concerns. And that is just pure speculation, and we don't have juries do that. In fact, this case sort of proves that point. There was a robust debate between a number of physicians about whether she does have something to worry about. 03:51PM

So again, to sort of speculate about what a physician in Savannah, Georgia, would have told her in respect to a visit about this, it just gets way too far into a territory that we just don't have the juries look at. 03:52PM

THE COURT: Well, let me ask you this question, Mr. Clark: The plaintiff did testify, according to my notes, that she started worrying about the strut when she learned it was in her lung. She testified in her deposition that she was going to go see Dr. Cooper to see if it was a mental thing or if it was actually the strut. She has not done that, hasn't seen Dr. Cooper. She hasn't seen any doctor to check on the strut. 03:52PM

It seems to me what you are arguing is that a failure to mitigate defense requires proof of two things: One is that there was some action the party could have taken to reduce damages; and the second is that had they taken that action it actually would have reduced damages. I think your point is that there's no evidence of the second of those two elements. 03:53PM 03:53PM

MR. CLARK: That's correct, Your Honor. It would be speculation.

THE COURT: What is your response on that, Ms. Helm?

MS. HELM: Your Honor, the jury charge as stated under Georgia law does not require the second element. It simply requires that they use the practice of ordinary care and diligence to mitigate the damage. It does not require a finding. And the charge is not asking the jury to make a finding. 03:54PM

THE COURT: But look at the last sentence. If you believe that by use of such care she could have reduced the damages. What evidence is there that she could have reduced the worry? 03:54PM

MS. HELM: Well, Your Honor, you are asking us -- that's, in fact, asking us to prove a negative. We didn't call Dr. Cooper because he never treated the patient. I think there's significant testimony in this case by the experts on both sides that the strut is stable. Dr. Muehrcke admitted to it. Dr. Hurst admitted to it. Dr. Stein admitted to it. 03:54PM

So what the charge is saying to the jury is you have to use reasonable care to mitigate the damages. The defendant doesn't have to prove that if you did that, everything would be better. It, in fact, instructs the jury that if you believe that such care would have reduced the damages you can determine that. Doesn't require a finding that it would reduce the 03:54PM 03:55PM

damages.

THE COURT: Thanks.

Mr. Clark, there has been testimony from some doctors like Dr. Moritz that we just listened to that this is a serious problem that a patient should follow. Presumably talking to that doctor would not have necessarily alleviated her worries. But she also testified herself that the doctor at Memorial Hospital told her the strut was safer where it was and there was no need for follow-up. 03:55PM

MR. CLARK: That's true, Your Honor. 03:55PM

THE COURT: So it seems to me a jury could, if they have competing opinions from doctors about whether or not it's something to worry about, and couldn't the jury say well, we think if she would have talked to a doctor she probably would have been reassured because we found more reasonable the testimony from the doctors that this really isn't something to worry about. 03:56PM

MR. CLARK: I don't think so, Your Honor. I think that the point you have identified is appropriate for the jury's consideration when they are determining whether she has been damaged, and if so, how much to award her. That's one part of it. But I don't think that we get there by having competing experts in here talk about what is reasonable when you are looking at the actual mitigation of damages is going to Dr. Cooper, which is the remedy, I guess, that is proven or 03:56PM 03:56PM

that there's evidence establishing that she could have availed herself of. But the jury would be left to guess at what Dr. Cooper would have told her. And the jury has heard no evidence other than Dr. Cooper, I think, is a family doctor, what he would know about this thing. He might have referred her to a specialist who may have said one thing or may have said another thing. But again, we're getting into conjecture. And I just don't think that's appropriate for a mitigation of damages instruction. It doesn't really fit with the evidence in this case. 03:56PM 03:57PM

Usually when we see this it's a preexisting condition issue or someone who is overtreated or you have got a property damage claim and the person didn't return the rental car fast enough. But when you are talking about fear, there has to be some evidence that had she availed herself of the remedy the defendants say she should have that that would have given her some relief. And we know she talked to one doctor and it didn't give her any relief. 03:57PM

THE COURT: All right. Thank you.

My determination under Rule 50 on a defense or a claim is to consider whether the jury has sufficient evidence in front of it that a reasonable jury could find in favor of the party that's asserting the claim or defense. And if there is enough evidence, a reasonable jury could make such a finding then I can't grant a Rule 50 motion. 03:57PM 03:58PM

My conclusion here is that there is enough evidence for a jury to conclude that she was worried. She did consider going to see a doctor, and it has heard evidence from some doctors there was nothing to worry about. I think that's enough evidence for a jury to conclude had she gone to see a doctor it would have alleviated her worries. I don't know if is the jury will find that way, but I think there is evidence in the record that would support such a finding and therefore, I'm going to deny the Rule 50 motion on the failure to mitigate claim. 03:58PM

So I will take the question mark out after Instruction Number 20, and I am going to delete Instruction Number 18, which is the assumption of risk defense. And we'll renumber the instructions.

Let me make a couple of other comments about jury instruction issues. 03:58PM

MR. NORTH: Your Honor, at some point I need two minutes to renew a Rule 50 motion also for the record.

THE COURT: Okay. Why don't we do that now.

MR. NORTH: Your Honor, at the conclusion of all the evidence we would simply renew the same motion we made at the conclusion of the plaintiff's case where we moved for judgment as a matter of law on the plaintiff's design defect claim, on the warning claim, on the claim for future pain and suffering because of the absence that it was -- of evidence that was more 03:59PM 03:59PM

likely than not there would be any complications.

And on the punitive damage claim, I would like to just incorporate all the arguments I made at the conclusion of the plaintiff's case so as not to reiterate those, repeat those at this point. 03:59PM

But we still believe that Rule 50 relief is appropriate for those four reasons. We think it's even more so after we have heard the defense case with regard to the punitive damage claim since the plaintiff's entire punitive damage claim is premised on an assumption that the rates of 03:59PM Bard complications are in excess of the rates of competitive filters. There's been affirmative evidence as a part of the defense case, including this Rule 1006 summary that the plaintiff introduced today that show very low rates of complications with regard to the Eclipse, and they produce no 04:00PM affirmative evidence of excessive complication rates with the device. And therefore, we don't believe they meet the clear and convincing standard of egregious behavior necessary for a punitive award.

So for that reason and the reasons stated at the 04:00PM conclusion of the plaintiff's case, we would renew our motion.

THE COURT: All right.

MR. MANKOFF: Your Honor, I believe that the evidence has become stronger during the presentation of the defense case. First of all, we continue to reject the proposition that 04:00PM

we're required to prove that the rates of fractures for the Eclipse Filter are higher than for competitor filters, but we believe we have done that.

Dr. Tillman testified that if you have a design defect you need to correct it and that if the complication that is experienced in a particular device is different, or unexpected, that that needs to be disclosed in the labeling. So simply for that reason alone, you have evidence of an inadequate warning because we do have evidence of this unique problem of caudal migration. 04:01PM

We heard that the instructions are misleading, and that the warning needs to take into account the severity of the harm as well. Bard has also made a false comparison, continues to make a false comparison, between the rates in SIR guidelines and the reported rates. As we have heard time and again, if you are looking at reported rates you have to take into account underreporting and essentially multiply the rate by 100 to make a proper comparison. 04:02PM

We saw from the Eclipse trial that the rates went into -- when you have a clinical trial the rates went into the teens. And the overall rate, I believe, when you add up the fracture, migration, perforation, and tilt, was approximately 28 percent. 04:02PM

There are charts in evidence showing that even looking at just reporting rates, Exhibit 1940 shows that the fracture 04:02PM

rate for the Eclipse Filter when it was first put on the market was higher than 5 out of 8 of the competitor filters. And we heard that the fracture rates go up as time goes on.

So we saw from the studies that if you look at a short-term like with the EVEREST trial, just five months the rate might be 1 percent. But if you go out two years it jumps to 12 percent and the studies that project out to five years show fracture rates up to 38 percent with the G2 slash Eclipse line of filters. Dr. Moritz just testified looking at a study that the Bard fractures were more common than with other filters. 04:03PM 04:03PM

If the Court has no questions we would rest on that evidence.

THE COURT: All right. Thanks. I'm going to deny the Rule 50 motion for the same reasons I did at the close of the evidence. 04:03PM

All right. Let's talk about jury instructions for a moment. Defense counsel, you were going to consider plaintiff's proposal that there be a link between instructions 14 and 16. Where are you on that issue? 04:04PM

MR. NORTH: Your Honor, we have decided that that would be okay. We do believe that the Court's suggestion that it go in the negligent design charge as opposed to the strict liability seemed to make more sense to us. But we thought that was okay. 04:04PM

We also thought that if you were going to do it there the same sort of addition might be need to be made to the negligent failure to warn.

THE COURT: My thought has been on this issue we ought to put it in both places -- not, I'm sorry, not negligent failure to warn but we ought to put it in both Instruction 14 and 16 to make clear that the jury must find that the Eclipse was defectively designed. 04:04PM

But we also ought to do it in the verdict form. We ought to also make clear that if they find as to one of those claims that it's not defectively designed they should make the same finding to the other so that they are not mislead by the jury form thinking they can separate those two. 04:05PM

Does that make sense to plaintiff's counsel?

MR. CLARK: It does, Your Honor. 04:05PM

MR. NORTH: Yes, Your Honor.

THE COURT: Okay. So the language that you had proposed, Mr. Clark, was on Instruction 14, you may not find that the Eclipse Filter was negligently designed unless you also find that the design of the Eclipse Filter was defective. 04:05PM I want to consider that a little more as to whether I want to reword it at all. But I will have that for you in the morning. And we'll have the same language on 14 and 16 so you can look at it and comment on it before the instructions. And we'll also make a change to the verdict form for you to review on 04:06PM

that issue tomorrow morning as well.

With respect to the damages instruction, the question that I wanted to ask was of defense counsel. The paragraph that I understand defendants have proposed to be added to Instruction Number 19 in red, on the first page is changed by 04:06PM
plaintiff simply to say that you must find that the evidence shows that it is more likely than not that Mrs. Jones will incur future pain and suffering.

And the way the defendants had phrased it is that plaintiff must show with reasonable medical certainty. What is 04:06PM
the basis for -- I mean, in light of what we say in Paragraph 2 that burden is preponderance of the evidence. What is the basis for defense's suggestion that the burden has to be with reasonable medical certainty?

MS. HELM: May I approach the podium? 04:07PM

THE COURT: Yeah.

MS. HELM: Your Honor, if you look at the paragraph -- two paragraphs above that that says Mrs. Jones seeks to recover, and the pattern charge says if you find that the evidence shows with reasonable certainty that she will sustain 04:07PM
future medical expenses, that's where the reasonable certainty language came from because that's the language in the pattern charge. So that's why I chose the language reasonable certainty.

And then there's case law in Georgia that says that it 04:07PM

requires expert testimony to show that there's a need for future medical care. Her future pain and suffering claim is based on the ability -- on her future medical care. So I'm relying on *Womack versus Burgess*, B-U-R-G-E-S-S, at 200 Georgia Appeal 347. And there's a whole line of cases that talks about what's required, like a doctor can't say there's a 50/50 likelihood. It has to be a greater likelihood. 04:08PM

So I actually chose the language of reasonable certainty based on the language in the charge, and I added the term "medical" based on the case law in Georgia. 04:08PM

THE COURT: Okay. What's the response from plaintiff's counsel?

MR. CLARK: Your Honor, I think that the medical expenses issue is different because there needs to be some definition of what those expenses are. The jury can't just pick a number out of the air. So that makes sense to us. 04:08PM

I did review the *Womack* case that Ms. Helm was kind enough to send me, and fortunately it's short so I think I could understand it. And it doesn't talk about medical certainty in terms of those magic words. It does talk about in citing some other cases in which the Court ruled, for example, that denied relief when there was established only a possibility and not a probability of a causal connection. So again, this case is talking about probability which is what we're telling the jury in Paragraph 2. 04:08PM 04:09PM

So I think it would be very confusing to the jury to have a new term that is not defined anywhere else in the instructions that it somehow has to apply in deciding whether she is likely to have future pain and suffering. And I think the evidence on the future pain and suffering is in front of it and it's like any other issue that we have the burden on, we should establish it's more likely than not or preponderance of the evidence. 04:09PM

THE COURT: I will read the *Womack* case and have the instruction for you to look at tomorrow morning at 8:30. 04:09PM

On the last paragraph that the defendants propose adding, I should say the last two sentences, plaintiffs propose for the last paragraph, that seems to me to be a restatement of the proximate cause requirement that is clearly included in the instructions before that. So it looked to me to be unnecessary, but I want to get defense counsel's reasons for proposing it before I strike it out. 04:10PM

MS. HELM: I really wasn't --

THE COURT: Before I consider striking it.

MS. HELM: That's okay. I really wasn't trying to be duplicative, Your Honor. I believe that there are some preexisting conditions here. And you are instructing the jury that Bard takes the plaintiff as they find her, but at the same time, to the extent that she has preexisting conditions, those can't be -- that were not attributed to the filter or not 04:10PM

exacerbated by the filter, those should not be considered by the jury. So Bard cannot be responsible for those preexisting conditions.

I actually pulled that language out of the pattern charge and so it may need a phrase or a sentence that I left out to make it clear. But that's what I was referring to there. 04:10PM

THE COURT: All right. Mr. Clark, you think preexisting conditions are adequately covered elsewhere, and if so, where? 04:11PM

MR. CLARK: Your Honor, I think just in the sentence right above the language Bard seeks to add: Thus, if you find that Mrs. Jones's injuries were increased by her existing physical condition, so again, it's a predicate that they have to find to the extent that they are looking at the preexisting issues they have to find some type of change or increase in them. That's a predicate for this finding, and that's what's instructed there. So I think to add another causation issue on top of that would be a restatement of instructions given elsewhere which I think they appear in Instructions 14 through 17 in terms of proximate cause and borders into comment on the evidence. 04:11PM 04:11PM

THE COURT: What if we were to do this: Make it clear that in this final paragraph, that plaintiff can recover for exacerbated conditions but not for pre-existing conditions. 04:12PM

What if we were to, in the sentence that you just referred to, Mr. Clark, it says: If you find that her injuries were increased by her existing physical condition you may award damages for those increased injuries provided you find they were proximately caused by Bard. 04:12PM

What if we then changed the next sentence and deleted the final one so the next sentence says: However, no plaintiff may recover for injuries or disabilities that are not proximately caused by the defendants. So you are sort of completing the thought that's in the preceding paragraph. 04:13PM

MR. CLARK: I don't love it, but I think it's fine.

THE COURT: Ms. Helm.

MS. HELM: I agree, Your Honor.

THE COURT: Okay. That's what we'll do. I think it does complete the idea stated in the sentence that begins with "thus" and will clarify for the jury. 04:13PM

MS. HELM: Your Honor, I actually have an additional request to -- request to charge Number 19 in light of the rebuttal testimony.

THE COURT: All right. 04:13PM

MS. HELM: I believe that on the first page of the instruction -- sorry. In Georgia we call them charges. In the paragraph that says: Ms. Jones seeks to recover, it's in the middle of the page, I believe after that sentence and before the "if you find" sentence that there should be some 04:14PM

instruction to the jury that she is not seeking medical monitoring or routine medical care, that the only future medical expenses she's seeking are either a percutaneous retrieval or the surgery. And I haven't crafted that without it being a comment on the evidence. But I do believe that that instruction is warranted there. 04:14PM

THE COURT: Mr. Clark.

MR. CLARK: Your Honor, I think the instruction as written is very clear that she's only seeking medical expenses that may be incurred in the future. The only evidence of future medical expenses are those presented by Sims and White -- I'm sorry, Lora White's report, which is basically for the two future surgeries. There has been no presentation of evidence relating to medical monitoring. 04:14PM

THE COURT: What about the testimony you just presented from Dr. Moritz that said he thinks she should receive regular follow-up with a doctor in the future and that's what he would advise her to do. That would be a future medical expense. 04:15PM

MR. CLARK: Right, but what this instruction says is they have to -- the evidence shows with reasonable certainty that she will sustain medical expenses. So I think the instruction covers it. We're certainly not going to argue anything about monitoring. 04:15PM

THE COURT: Could the jury reasonably say well, Dr. 04:15PM

Moritz said she's going to get -- she needs to be monitored. She's going to get that expense with reasonable certainty. We're going to award her medical monitoring damages.

MR. CLARK: I don't know how they would make that calculation. They would have to guess at something. And that's the only thing they are going to hear from us as far as future medical expenses are what you heard from Nurse White. 04:15PM

THE COURT: What if we -- what if in the second sentence of that paragraph we said something like, if you find that the evidence shows with reasonable certainty that Mrs. Jones will sustain future medical expenses for removal of the filter fragment, comma, proximately caused by the actions of Bard, comma. 04:16PM

MR. CLARK: No objection.

THE COURT: So it's precise to what you are seeking. 04:16PM

MR. CLARK: That would be fine with the plaintiff.

MS. HELM: I think that resolves it, Your Honor.

THE COURT: Okay. All right. Any other comments on the damages instruction?

MR. CLARK: Not for the plaintiff. 04:17PM

THE COURT: With respect to the FDA instruction, I'm still a bit undecided but I want to get the plaintiff's reaction to a concern that I have. The way you have proposed the instruction in the version that was handed to me today by Traci that I assume came from plaintiff's counsel, we would say 04:17PM

in the second sentence of the third paragraph that the FDA does not make a determination that the device being cleared is safe and effective. My concern is that the statute, 21 United States Code Section 360c(i)(1)(A)(ii), says that one the ways the FDA can decide that a product is substantially equivalent 04:18PM
is if the proponent, quote, "demonstrates that the device is as safe and effective as a legally marketed device," close quote.

And the regulation, which is a 21 CFR 807.100, subpart (b), says that substantially equivalency can be based on a finding that, quote, "The data submitted establishes that the 04:19PM
device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device," close quote. 04:19PM

So there are situations where safety and effectiveness in a comparative sense are considered by the FDA in a 510(k) submission. And it seems to me if I were to instruct the jury on the 510(k) process, I would have to include that because that's what the law allows them to do. And I worry that's just 04:19PM
going to muddy the waters more if I start down that road of telling them how and in what way the FDA can consider safety and effectiveness.

That's my concern. I'm interested in a response of plaintiff's counsel. 04:20PM

MR. CLARK: I understand the concern, Your Honor. The concern we have is the only regulatory expert the jury heard from was Dr. Tillman who said this is what the FDA does. It makes a determination that it is as safe and effective as a different device. So that's the impression the jury is left with. And I think the water is already muddied in that sense. 04:20PM

So I think there needs to be some instruction that what we have here in a 510(k) is a different threshold. There are different considerations. And maybe it's as easy as saying, you know, that that is one of the factors that can be considered. But it's -- but to kind of leave that impression, and again, we keep hearing it in the case. I didn't write down what the context of the question was. But there was some discussion, I think even from Mr. Randall today, about FDA approval. And those words keep getting bandied about. So I think that's very prejudicial to the plaintiff. 04:20PM 04:20PM

THE COURT: So my notes show that on this point you are talking about, Mr. Clark, Ms. Tillman was reading from the FDA guidance document on the 510(k) process which is Exhibit 7758. And she was reading from Page 9 that sets forth the substantial equivalent standard which said that the standard differs from the PMA standard which requires independent determination of safety and effectiveness. And then Ms. Tillman testified the FDA does not make a safety and effectiveness determination on a 510(k), but it can find that 04:22PM 04:22PM

the device is as safe and effective as the predicate device. And then she said 510(k)s are fundamentally about safety and effectiveness. I assume that's the concern you have.

MR. CLARK: Well, that and her statement in response to Mr. North's question: And to be clear, does the FDA make the same pronouncement with regard to 510(k) devices like IVC filters? The answer was no, it instead makes a determination that the new device is as safe and effective as the predicate device which is a different finding than in a PMA. And again, it's basically saying they make a determination that it is as safe and effective. They may have reached their determination that it is substantially equivalent through that process, but they aren't making a determination that device is as safe and effective. And that's the conundrum we have. 04:22PM 04:23PM

THE COURT: It seems to me what the regulation I just read says is that it says: FDA will determine that a device is substantially equivalent to a predicate device using the following criteria. It's intended for the same use; it has the same technological characteristics; it has different technological characteristics. And I'm now quoting again, "The data submitted establishes that the device is substantially equivalent to the predicate device and contains information including clinical data if deemed necessary by a commissioner that demonstrates that the device is as safe and effective as a legally marketed device." 04:23PM 04:24PM 04:24PM

So it seems to me the FDA in those instances looks at the submission and says this data demonstrates that it is as safe and effective.

MR. CLARK: That's a list of factors that are considered, right. I mean, that is one of the things that is considered. 04:24PM

THE COURT: True. Well, so my concern is, if I try to instruct the jury on this, it seems to me I need to essentially read to them what's in the regulation with the various factors that are to be considered which would say this is one that can be considered. 04:25PM And the question I have is does that help? Does that clarify the issue you are trying to clarify?

MR. CLARK: I think it does, Your Honor, because it shows that there are many considerations and it's distinct from the PMA process. 04:25PM And it's kind of similar to what we have in Instruction 14 that there are a variety of factors that get examined. And I think what we heard in the Booker trial was that Ladies and Gentlemen of the jury, the FDA looked at the same evidence that you are seeing in this case and made a determination this is safe and effective. 04:25PM And it would be very fair and helpful for us to be able to argue that based on the instruction that there are a variety of factors that the FDA looks at of which safety and efficacy can be one.

THE COURT: All right. Response from defense counsel.

MR. NORTH: Yes, Your Honor. For the reasons the 04:25PM

Court alluded to, we believe the third paragraph is not a complete statement of the law. We do believe it's not necessary to give any instruction, but if the Court did, we believe the third paragraph should be replaced as the Court just suggested by the lengthy standard and more detailed synopsis that the Court read. Because the fact of the matter is, Dr. Tillman's testimony was correct. Based on the regulations and the guidance that the Court just read, the FDA does make a determination in the 510(k) context whether the new device is as safe and effective as the predicate device. 04:26PM

THE COURT: Well, I'm not sure I agree with the way you say that, Mr. North. Because if the FDA finds that the device has the same technological characteristics as the predicate, it can find substantial equivalence without considering safety and effectiveness because it's disjunctive. 04:26PM It says either that or. So I think part of plaintiff's point is yeah, they can consider it, but we don't know if they did in this case. We don't know whether or not the FDA blessed or said that it's as safe and effective because they could have based it on the fact that it had the same technological characteristics. 04:27PM

MR. NORTH: But I'm not certain, Your Honor, that reading of that would be consistent with the statute that the Court read, which didn't seem to so limit it as I read it.

THE COURT: The statute also says -- I won't read you 04:27PM

the whole thing. It's long. But for purposes of the substantial equivalence determination, the agency finds that the device, one, has the same technological characteristics as the predicate device; or, two, finds that it's as safe and effective. It's disjunctive in the statute as well. 04:28PM

I think what I'm going to do is my best to in plain English incorporate these factors into an instruction for you to look at in the morning. Because I do think that it's relevant for the jury to know that FDA can clear a product under 510(k) without deciding that it's as safe and effective 04:28PM if they find it is -- has the same technological characteristics.

MR. NORTH: Your Honor, if I could just add, we would also object to the Fourth paragraph of that charge as we believe that is a clear comment on the evidence and the Court 04:28PM should conclude that charge with the third paragraph.

THE COURT: I understand that. I will have a proposed instruction for you all to look at in the morning on that.

Are there other jury instruction issues we need to cover? 04:28PM

MR. CLARK: Not for the plaintiff, Your Honor.

MS. HELM: None for the defendant, Your Honor.

THE COURT: Jeff, are we missing any?

MR. CLARK: Just to be clear, though, Mr. North had offered a suggestion that perhaps we make some more change to 04:29PM

the failure to warn strict liability and negligent failure to warn. We vehemently disagree with that.

THE COURT: I understand that. I'm not going to do that. I'm going to do it on the two design defect claims.

All right. How long do you all think your closings will be in the morning? 04:29PM

MR. NORTH: Your Honor, while they are looking, I would say I think ours will be an hour to hour 15. I certainly will not use the three hours I have left.

MR. O'CONNOR: Probably an hour on the plaintiff. 04:29PM

THE COURT: Well, the plaintiff has an hour and 13 minutes left in the case.

MR. O'CONNOR: I will work with that.

THE COURT: Keep that in mind.

All right. My plan then will be to instruct the jury, 04:30PM go right into plaintiff's arguments, take a break between the two, have defense arguments, any rebuttal, and then break for lunch. So we'll get all the arguments done before the lunch hour.

Okay. We'll see you at 8:30. 04:30PM

(Proceeding recessed at 4:30 p.m.)

**C E R T I F I C A T E**

I, LAURIE A. ADAMS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 31st day of May, 2018.

s/Laurie A. Adams
_____
Laurie A. Adams, RMR, CRR